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. This Directive amends Directive 2001/83/EC on the Community Code relating to medicinal products for human use.

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 setting out the details relating to the unique identifier.

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;
- The modalities for verification of the safety features;
- The provisions on the establishment, management and accessibility of the repositories system in which information on the safety features is to be contained;
- 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;
- 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.

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. 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.

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/EU12 may now be partially outdated and in need of updating.

7. The adoption of the delegated act is scheduled for 2014. 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 €50million 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.

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. 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. 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.

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?

We have a strong preference for option 1/2 (harmonisation through regulation) which creates a uniform and predictable obligation for all manufacturers. Almost all of the existing serialisation initiatives undertaken by manufacturers are sufficiently similar that a suitable single standard (GS1) should cover existing circumstances. The alternative, option 1/1, could allow some manufacturers to choose solutions which are not universally compliant.

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, 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

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

The GS1 system of standards is widely accepted and provides the necessary unique numbering for EU-wide use. Using a Global Trade Item Number (GTIN) framework for the manufacturer product code will ensure the widest possible usage. Manufacturers need minimal complexity and maximal compatibility in their global supply chain operations, therefore the EU-regulated identifier should adhere as closely as possible to global standards.

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 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.

The advantage of the proposed inclusion of batch and expiry date in the serialisation number is principally that the automatic reading of data will increase the number of data points recorded in the supply chain and facilitate more exact recalls.

A possible disadvantage of including this data in the code could be that the code must then be printed at the point of packing. It is not possible to pre-print codes onto packaging, as could theoretically be possible if only GTIN and serial number was required in the code (and batch and expiry were printed separately as is currently the case).

On balance, the inclusion of batch and expiry information has benefits which outweigh the disadvantages. Most companies are in any case printing variable codes online to comply with CIP13 requirements in France and Turkish serialisation rules.

(c) National reimbursement number

25. Directive 2011/62/EU lays down exhaustive rules on labelling for medicinal products as regards authenticity and identification. 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.

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)

XXXXXXXXXXXXXX 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.

The simplest option would be to require all governments to use the serialisation number (option 1). This provides the necessary uniqueness of numbering which is needed for reimbursement without the added complexity of additional numbers. Removing national numbers also allows more easily for the use of multi-market packs where permitted and feasible (Austria/Germany for example), potentially lowering manufacturers' packaging costs.

For practical and political reasons, we recognise that it may be necessary to have a transition period during which national number systems are phased out.

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. 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:

- costs for reading devices for the different carriers;
- costs for adapting packaging lines of medicines packaged for the EU market.

Linear barcode:

Benefits

- Readable by existing retail equipment (laser-scanning) and camera-based scanners.
- Minimal upgrade costs at pharmacies.

Disadvantages

- Requires relatively large amounts of pack space to convey the necessary serialisation information, as the available data density is not as high as with 2D codes or RFID.
- It is technically difficult to print long barcodes, with variable information, on the production line. Typically, the existing bar codes denote stock-keeping unit (SKU) information only and are pre-printed on “flats” or labels. Therefore, the use of linear barcodes as the serialisation identifier is inherently problematic and effectively precludes the inclusion of batch and expiry data (see consultation 3).

2D codes:

Benefits

- Data density is far higher therefore large amounts of data can be fitted onto small pack areas.

- Formats and printing standards are well established. The GS1 ECC200 format is widely accepted and adopted.
- Codes can be printed at high production line speeds (>300 packs per minute) with high accuracy.
- Codes can be applied by laser ablation (removal of dark ink by a high-speed laser, leaving a white-on-dark pattern of dots) or inkjet printing (addition of black dots to a white substrate)
- Equipment is well-proven, reliable and available from a number of manufacturers.
- Capital costs of coding and vision equipment (variable) and incremental costs per code (typically <1 cent Euro) are acceptable. Many manufacturers have suitable equipment on some of their lines to provide 2D coded product for France and Turkey.
- There are very few limitations regarding substrates or types of product on which the codes can be used (cf RFID below).
- Costs of retail readers are reasonable (up to several hundred Euros)
- Consumer verification is possible. Most smartphones now have 2D code reading capability.

Disadvantages

- Line of sight is required. That is, the reader must have an uninterrupted path to the code. Codes cannot be read through opaque packaging or in aggregated form (shipping cartons, pallets etc) without unpacking. This could place heavy burdens on distributors and other intermediaries if all codes are required to be read at each change of ownership or custody in the supply chain. The EFPIA proposed model of end-to-end verification (at manufacturer and pharmacist, with optional checks in between) addresses this issue.
- Upgrades to pharmacy scanning systems may take time to implement. As noted above, the scanners needed for 2D codes will read linear barcodes but not always vice versa. Some pharmacists may object to the perceived cost burden.
- Data cannot be added to codes once printed. The transactional data is held in databases (either centrally or distributed) and the code is simply the access key to that information. Therefore, 2D code systems require internet access – typically in real time although offline modes with batch reconciliation by dial-up are possible.

RFID:

Benefits

- Line of sight is not required. In theory, RFID tags can be read through packaging and multiple tags in aggregated form can be read simultaneously. This removes the need for unpacking of pallets and cases during verification of the codes on individual packs in transit. Therefore, RFID could enable a fuller pedigree or transactional history to be generated for each shipment by automatically capturing information as items enter and leave transit points.

- Certain “active” RFID tags have read-write capability. Therefore data can be added to the tag itself and the product can carry a complete history that can be accessed without referral to a distant database.

Disadvantages

- Cost. The incremental cost per tag for RFID is typically around 20 cents Euro, much too high to be practical or affordable for either branded or generic products. Readers are more expensive than for linear or 2D codes.
- Availability. RFID infrastructure is not widely installed in retail environments.
- Consumer verification is difficult or impossible without specialist readers.
- Compatibility. The interference from liquids may render RFID unusable in some situations. There are also concerns about interactions with delicate biological products.
- Privacy. Concerns have been expressed about the potential privacy issues and the ability of unauthorised persons to gain access to information about the medication that a person is carrying (eg with a view to subsequent theft). This can largely be addressed by “killing” the tag during the dispensing process.

We strongly support the use of (ECC200) format 2D codes as the data carrier for the unique identifier.

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).

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.

45. For other actors in the supply chain, the detailed procedures for verification are to be established in the delegated act following an impact assessment. 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.

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?

There must be agreed mechanisms for pharmacists to return product to the supply chain, in the event that a pack is erroneously dispensed, or dispensed to in advance but not subsequently picked up by the customer. These mechanisms must preclude, insofar as is possible, the potential for fraud.

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.

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.

The key point about these three options is that they are an evolution of the same process. Staring with Option 2/1 (pharmacy check-out only) would allow a relatively simple process to be rolled out more quickly. In time, this could be upgraded to option 2/2 and then option 2/3. The latter option (universal verification along the supply chain) would be very onerous on distributors for the reasons outlined under 2D codes above, namely the need for greater complexity and the reduction in turnaround speed. Option 2/3 would require either full unpacking/verification/repacking or an aggregated system of nested and linked codes for unit packs, shipping cartons etc.

Our preference is to start with Option 2/1 as the simplest option and concentrate on universal application of the system across the EU, then upgrade to option 2/2 with random checks by distributors. Of course, distributors could verify codes on a voluntary basis even under option 2/1. It should be noted that a too-frequent mandatory random check requirement (a "heavy" version of Option 2/2) could actually be more complex and worse for distributors than a universal verification system (Option 2/3)

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. The delegated act shall contain provisions on the establishment, management and accessibility of the repositories system, following an impact assessment.

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.

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.

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).

We strongly support option 1 (stakeholder governance). There is a joint agreement between EFPIA, GIRP and PGEU which unites the views of manufacturers, distributors and pharmacists in this matter. The stakeholder governance model is almost certain to be less expensive than the EU or national models, minimising the costs which need to be passed on to consumers. This is because the system can rely on routing queries securely to manufacturers' databases, with no central database required. In any case, manufacturers will need to have their own databases to store their serialisation information, so this option represents the least extra investment.

Option 2, a large, EU-managed infrastructure project with a single central database, is likely to be difficult to set up and provides more risks than the distributed model governed by the stakeholders who will have to use the system (option 1). The central database for option 2 will need to be extremely secure and located in a secure and disaster-resistant location.

The third option, a network of national systems, is arguably the worst of all worlds – an unwieldy and difficult-to-connect system with local idiosyncrasies and unnecessary complexity for all stakeholders.

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?

The protection of sensitive information from dissemination to competitors is of paramount importance. However, the use of some (suitably aggregated) data by the original manufacturers could help to improve supply chain efficiency and thereby eventually lower drug costs for buyers and patients. Using appropriate database controls, it should be possible to segregate data in such a way that security is compatible with limited usage of data in this way.

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?

The protection of personal data is important but none of the potential modalities of the verification system are likely to pose a risk in this regard.

Re-packaging is a more serious concern. If the manufacturer has chosen an enhanced security option (eg printing the unique identifier using a security ink containing a covert taggant) then the repackager should be obliged to replicate the same feature or at least to approximate the same level of security. Otherwise, the paradoxical effect of the proposed new system could be to disincentivise the use by manufacturers of all security features except the proposed unique identifier. This may be to the detriment of patient safety in the event that codes become widely copied.

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').

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').

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:

• 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 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.

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?

The concept of a “white list” is entirely unnecessary and mistaken, in our view. A far simpler system would be to include ALL prescription medicines. By omitting some prescription drugs from the unique identifier system, the Directive could make these drugs attractive (easier) targets for counterfeiters.

The implied two-year lead time for any amendments to the Delegated Act (and thus to the white list) is far too slow to react to any change in counterfeiting patterns that may occur after the initial list is published.

The criteria given for establishing products on the white list are entirely spurious.

There is no evidence that previous incidents of counterfeiting predict which products will be targeted in the future.

Price is also not a reliable indicator. Products such as cheap, over-the-counter branded painkillers are routinely faked in other regions of the world.

The seriousness of the condition to be treated is also not relevant. Toxic counterfeits can kill, whether the original brand is intended for a mild or life-threatening condition.

We are also concerned that the Directive implies that white listed products may not bear an optional unique identifier (at the manufacturer’s discretion). This means that manufacturers may have to turn coding systems on and off during production and creates unnecessary complexity. The cost of the unique identifier and verification system can be best be minimised by making the criteria as simple as possible and their application as uniform as possible.

Finally, the white list process requires the pharmacist to know (or check) whether the product should have a code or not. This is an unnecessary complication to pharmacy workflow and a potential security weakness.

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:

Price
High price: 5 points; Low price: 1 point;

Volume
High volume: 5 points; Low volume: 1 point

Incidents in the EU or third country
Several incidents: 5 points; No incident: 1 point

Characteristic of the product
Characteristics indicate risk of falsification: 5 points; Characteristics indicate no risk of falsification: 1 point

Severity of the conditions intended to be treated
Conditions severe: 5 points; Conditions not severe: 1 point

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 'blacklist'.

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.

The scoring system for white listing is entirely based on false premises (see our earlier argument) and we advocate that all prescription medicines should be included without exception to reduce uncertainty and complexity.

The scoring system for blacklisting of non-prescription products should be based most closely on ease of counterfeiting and on intelligence about previous and current incidents. A regulatory mechanism for more regular review of threats (see below) would be far more useful than the metrics above, which may give a false sense of security.

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.

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.

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.

We reiterate that the unique identifier system and the requirements for manufacturers should be as simple and unambiguous as possible. There must be an equivalent obligation for all manufacturers.

It should also be borne in mind that the EU is just one of the key regions in which manufacturers need to operate. The modern pharmaceutical supply chain is global and inter-regional trade and coordination is common. We urge those drawing up the Delegated Act to ensure that the technical requirements of the system are as harmonised as possible with likely traceability requirements in other major markets such as the United States, Brazil, China, India etc.