European Medicines Verification Organisation

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Summary of the Safety Features for Medicinal Products for Human Use

Questions & Answers - Version 22

Revised Q&As:

1.4. Question: Are there exceptions from the requirements for certain medicinal products to bear or not the safety features?

Answer: Yes. The list of categories of medicinal products subject to prescription which shall not bear the safety features are set out in Annex I of Commission Delegated Regulation (EU) 2016/161, while the list of medicinal products not subject to prescription which shall bear the safety features are set out in Annex II of the same Regulation.

1.22. Question: In case of parallel-traded packs, can parallel traders cover or remove the safety features of the original pack?

Answer: Parallel traders covering or removing the existing safety features are required to place equivalent safety features in accordance with Article 47a of Directive 2001/83/EC (see also Q&A 1.20). The new unique identifier should comply with the requirements of the Member State where the medicine is intended to be placed on the market (Article 17 of Commission Delegated Regulation (EU) 2016/161).

Furthermore, if the product code and/or batch number of the parallel-traded product change compared to the original product, parallel traders must place a new unique identifier after first decommissioning the original one. For further details on the requirements for batch numbers appearing on the packaging of medicinal products subject to parallel trade, see Q&A 4 under 'EU GMP guide part I: Basic requirements for medicinal products: Chapter 5: Production' on the EMA website.3 When placing an equivalent unique identifier, parallel traders are required to fulfil, inter alia, the obligations laid down in Articles 33, 40 and 42 of Commission Delegated Regulation (EU) 2016/161 concerning the uploading and keeping up to date of the information on the new unique identifier into the repositories system. In all cases, traceability must be maintained in the repository system in accordance with Article 35(4).

2.3. Is it possible to keep one-dimensional barcodes on the packaging of medicinal products for human use having to bear the safety features, when adding the two-dimensional barcode carrying the unique identifier?

Answer: Yes, provided that the presence of both barcodes does not negatively impact the legibility of the outer packaging. In order to avoid incorrect scanning by end-users, if possible, the barcodes should not be placed in proximity to each other, preferably on different sides of the packaging.

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2.7. Question: Is it compulsory to print the national reimbursement number in human-readable format?

Answer: The national reimbursement number or other national number should be printed in human readable format only if required by the national competent authorities of the relevant Member State and not printed elsewhere on the packaging. It should be printed adjacent to the two-dimensional barcode if the dimensions of the packaging allow it, unless national legislation provides otherwise.

2.12. Question: Is it allowed to place a QR code on the packaging of a medicinal product bearing the safety features?

Answer: Commission Delegated Regulation (EU) 2016/161 does not prohibit the placing of a QR code as far as it is not used for the purposes of identification and authentication of medicinal products. Marketing authorisation holders are however encouraged, wherever technically feasible, to exploit the residual storage capacity of the Data Matrix to include the information they would otherwise include in the QR code (see also Q&A 2.16). This would minimise the number of visible barcodes on the packaging and reduce the risk of confusion as regard the barcode to be scanned for verifying the authenticity of the medicinal product. Furthermore, in order to avoid incorrect scanning by end-users, if possible, the QR code should not be placed in proximity of the Data Matrix, preferably on a different side of the packaging.

2.21. Question: Is it acceptable to use stickers to place the unique identifier on the outer/immediate packaging?

Answer: As a rule the unique identifier must be printed on the packaging (Article 5(3) of Commission Delegated Regulation (EU) 2016/161). For medicinal products subject to parallel import and parallel distribution it is possible to use a sticker (adhesive label) provided that the sticker cannot be removed without being damaged and that the sticker fulfils the quality of the printing requirements set out in Article 6 of the Commission Delegated Regulation (EU) 2016/161 (case C-147/20, Novartis Pharma GmbH v Abacus Medicine A/S). In addition, for medicinal products other than those subject to parallel import and parallel distribution, placing the unique identifier by means of stickers can be accepted in the following circumstances: - No legal and/or technically feasible alternative exists (e.g. safeguard of trademark rights; glass/plastic immediate packaging without outer packaging; etc.); or - Competent authorities authorise it due to the marketing authorisation to safeguard public health and ensure continued supply. The placing/replacement of the unique identifier using stickers must be conducted in accordance with applicable Good Manufacturing Practice principles. Moreover all applicable labelling requirements in Directive 2001/83/EC must be met and the sticker must not impair the readability of other required labelling elements. The sticker should be tamper-evident, i.e. it should not be possible to remove it without damaging the packaging or the sticker itself or leaving visible signs. The unique identifier

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should not be printed on a separate sticker to the other labelling particulars unless agreed with the competent authority.

2.22. Question: Do human-readable headers (PC, SN, Lot, EXP, NN) have to comply with the provisions of the QRD-template?

Answer: Yes, preferably. According to the current of the QRD-template, the product code, serial number and national reimbursement number in the human readable code should be preceded by the letters "PC", "SN" and "NN". Batch number and expiry date should follow the abbreviations laid out in Appendix IV of the QRD-template.

7.7. Question: In Article 35(1)(f), does the upper limit of 300 ms for a repository to respond to queries also apply when multiple repositories are implicated in the query, for example in case of cross-border verification?

Answer: 300 ms is the maximum response time of an individual repository. When the verification/decommissioning operation requires the querying of multiple repositories in the repositories system, for example in case of inter-market transactions, the maximum response time is obtained by multiplying the maximum response time of an individual repository (300 ms) by the number of repositories involved in the query – for example, the maximum response time for a query involving national repository A, the hub, and national repository B would be 900 ms.

It should be noted that the system response time does not include the time needed by the query data to move from one repository to the other (which depends from the speed of the internet connection).

7.19. Question: Can a marketing authorisation holder delegate the uploading of the information laid down in Article 33(2) of Commission Delegated Regulation (EU) 2016/161?

Answer: Yes. Marketing authorisation holders (MAHs) may delegate the uploading of the information laid down in Article 33(2) to third parties (on-boarding partners (OBPs) by means of a written agreement between both parties. The MAH remains legally responsible for these tasks. In all cases, the MAH must ensure with a high level of confidence the accuracy, confidentiality and integrity of the data uploaded into the system. This includes, but is not limited to: procedures to ensure that uploaded data and actual batch properties correspond (such as, batch number, expiry dates, destination market, batch size), procedures for secure data exchange with the subcontractor and procedures to ascertain that data to be uploaded has not been corrupted in any way. Data uploading performed by means of infrastructures, hardware and software that are physically located outside the EEA is strongly discouraged.

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8.9. Question: Should marketing authorisation holders upload the unique identifiers for products with 2D barcodes released for sale or distribution before the date of application of Commission Delegated Regulation (EU) 2016/161?

Answer: Yes. According to Article 48 of Commission Delegated Regulation (EU) 2016/161, medicines released for sale or distribution before the date of application of this Regulation without a unique identifier may remain on the EU market until their expiry date, as long as they are not repackaged or relabelled after that date. If they are repackaged or relabelled after the date of application of the Regulation, the manufacturer must place safety features in accordance with Directive 2001/83/EC and Commission Delegated Regulation (EU) 2016/161.

This transitional measure does not apply for products which were released before the date of application of the Regulation with a unique identifier. The unique identifiers for such products should be uploaded to the system before the entry into application of the new rules. This should help to avoid alerts for genuine products released before the date of application of the Regulation due to lack of data in the repository.

Newly added Q&A(s):

7.21 Question: Should NCAs have access to all end-user information in the audit trail, including the names and addresses of end-users in another Member State?

Answer: Yes, all NCAs shall have full access to all audit trail data upon request. This includes information such as the corporate name and address of wholesalers and persons authorised or entitled to supply medicinal products to the public, who are involved in verifying the authenticity and decommissioning of a unique identifier.