**AIDE MEMOIRE FOR INSPECTION OF PHARMACIES***
**COMPLIANCE WITH COMMISSION DELEGATED REGULATION (EU) 2016/161 FOR SAFETY FEATURES**
**16 July 2020**

| **Area of operations / items** | **Questions/Show me** | **References (where applicable)** |
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| Connection to Repository System | Have you registered with the National Medicines Verification Organisation (NMVO)?<br>Show me the registration documentation.<br><br>Do you have a contract with the NMVO?<br><br>Is the pharmacy connected to the national repository system? What was the date of connection?<br><br>For chains of pharmacy outlets which are all part of the same parent company/legal entity, does each individual pharmacy location have its own connection to the repository, so that all transactions carried out within that location may be traced to the specific location/address?<br><br>Is software implemented for the verification and decommissioning of safety features?<br><br>Do updates to the software occur and is there evidence of these updates?<br><br>Does the pharmacy software generate a reminder of the obligation to verify and decommission the unique identifier (UI) at the time a pack is supplied?<br><br>Does the pharmacy software allow the release of a medicinal product pack without the verification process and decommissioning of the UI? | Articles 11, 25 DR |
| Technical Requirements | Was equipment required for the purpose of compliance with FMD requirements installed and is it functioning as intended?<br><br>Are all dispensing stations in the pharmacy equipped with a scanner?<br>Is the number of scanners etc. appropriate? | |
| Procedures/Instructions & Training | Are procedures and work instructions in place for all processes related to the requirements (e.g. verification and decommissioning, actions to be taken in the event of error codes etc.)?<br><br>Do relevant personnel have access to current procedures and instructions? | |

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| | Have relevant personnel received training in the procedures and activities related to the implementation of safety features?<br><br>Does this include training in the handling of technical alerts and how to deal with them?<br><br>Is there a document (electronic/paper copy) containing instructions for handling of alerts (including technical alerts) and how to deal with them, available to personnel anytime it may be necessary?<br><br>(*Note: The procedures/activities should be under the supervision of a pharmacist*) | |
| Verification of the safety features | Is the verification and decommissioning of the unique identifier performed for the supply to the public of medicinal products affected by the Regulation 2016/161/EU?<br><br>When verifying the safety features, are the following verified:<br>(a) the authenticity of the UI;<br>(b) the integrity of the anti-tampering device (ATD).<br><br>Request to see records of checks completed related to verification of UI.<br><br>Request to see overview of alerts related to verification of UI and actions taken.<br><br>At what time is the verification and decommissioning taking place in relation to supply? | Articles 10, 11 DR |
| Reversing the status of a decommissioned unique identifier | Under what circumstances is the reversal of the status of a decommissioned unique identifier to an active status permitted?<br><br>Is this covered by a procedure?<br><br>Does the procedure provide for the following:<br>(a) the person performing the reverting operation is covered by the same authorisation or entitlement and operates in the same premises as the person that decommissioned the unique identifier;<br>(b) the reverting of the status takes place not more than 10 days after the unique identifier was decommissioned;<br>(c) the pack of medicinal product has not expired; | Article 13 DR |

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| | (d) the pack of medicinal product has not been registered in the repositories system as recalled, withdrawn, intended for destruction or stolen and the person performing the reverting operation does not have knowledge that the pack is stolen;<br>(e) the medicinal product has not been supplied to the public.<br>(*Note: the system will not permit a-d above and alerts would be triggered*) | |
| Obligations of persons authorised or entitled to supply medicinal products to the public | Is the pharmacy verifying the safety features and decommissioning the unique identifier of the following medicinal products bearing the safety features?<br>(a) medicinal products in their physical possession that cannot be returned to wholesalers or manufacturers;<br>(b) medicinal products that, while in their physical possession, are requested as samples by competent authorities, in accordance with national legislation;<br>(c) medicinal products which they supply for subsequent use as authorised investigational medicinal products or authorised auxiliary medicinal products as defined in Articles 2(2)(9) and (10) of Regulation (EU) No 536/2014.<br>(d) Other situations as permitted by national law.<br>(*Note: the decommissioning in these cases is not for supply, but rather decommissioning to other statuses*) | Article 25 DR |
| Obligations when supplying only part of a pack | When only part of a pack of a medicinal product is supplied, are the safety features verified and the unique identifier decommissioned when the pack is opened for the first time? | Article 28 DR |
| Obligations in case of inability to verify the authenticity and decommission the unique identifier | Where technical problems prevent the verification and decommissioning of a unique identifier at the time of supply to the public, how is this situation handled?<br>Are there any records about these cases? | Article 29 DR |
| Actions to be taken in case of suspected falsification | Where there is reason to believe that the packaging has been tampered with, or the verification of the safety features indicates that the product may not be authentic, what arrangements are in place to ensure that the product is not supplied?<br><br>How are the relevant competent authorities informed and within what timeframes?<br><br>Is the pharmacy connected to any IT system for alerts management? | Article 30 DR |

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| | Is the pharmacy checking the status of the investigation in case of alert? | |

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