| **Part I: Commission Delegated Regulation (EU) 2016/161 - Legislative Requirements** | | **NMVO Response (including reference to supporting evidence submitted, where applicable)** |
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| | | **NMVO Name:**<br><br>**Member State:**<br><br>**Date Assessment Completed:**<br><br>**Name and Job Title of Person who completed Assessment:** |
| **Establishment of the repositories system** | | |
| Article 31.1 | The repositories system where the information on the safety features shall be contained, pursuant to Article 54a(2)(e) of Directive 2001/83/EC, shall be set up and managed by a non-profit legal entity or non-profit legal entities established in the Union by manufacturers and marketing authorisation holders of medicinal products bearing the safety features. | Provide registration number and copy of Certificate of registration of legal entity. |
| Article 31.2 | In setting up the repositories system, the legal entity or entities referred to in paragraph 1 shall consult at least wholesalers, persons authorised or entitled to supply medicinal products to the public and relevant national competent authorities. | How was it ensured that all relevant operators were consulted?<br><br>If available, provide records showing how input from relevant operators was taken into account. |
| Article 31.3<br><br>&<br><br>Article 31.4 | Wholesalers and persons authorised or entitled to supply medicinal products to the public are entitled to participate in the legal entity or entities referred to in paragraph 1, on a voluntary basis, at no cost.<br><br>The legal entity or entities referred to on paragraph 1 shall not require manufacturers, marketing authorisation holders, wholesalers or persons authorised or entitled to supply medicinal products to the public to be members of a specific organisation or organisations in order to use the repository system. | Were these provisions met and how can this be demonstrated?<br><br>It is expected that this information be made available to prospective clients through for example the website, terms and conditions, contract template etc. Provide details in this regard. |

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| Article 31.5 | The costs of the repositories system shall be borne by the manufacturers of medicinal products bearing the safety features, in accordance with Article 54a(2)(e) of Directive 2001/83/EC. | Provide details of the cost structure implemented. |
| **Structure of the repositories system** | | |
| Article 32.1 | The repositories system shall be composed of the following electronic repositories:<br>(a) a central information and data router ('hub');<br>(b) repositories which serve the territory of one Member State ('national repositories') or the territory of multiple Member States ('supranational repositories'). Those repositories shall be connected to the hub. | Is the repository a 'national' or a 'supranational' repository?<br><br>If 'supranational', which Member States does it serve?<br><br>Provide details to demonstrate the connection between the national repository and the European hub. |
| Article 32.3 | 3. The repositories system shall comprise the necessary information technology infrastructure, hardware and software to enable the execution of the following tasks:<br>(a) upload, collate, process, modify and store the information on the safety features that enables the verification of the authenticity and identification of medicinal products;<br>(b) identify an individual pack of a medicinal product bearing the safety features and verify the authenticity of the unique identifier on that pack and decommission it at any point of the legal supply chain. | Provide an overview of the system description/architecture detailing the physical and logical arrangements, data flows and interfaces/connections with other systems or processes. |
| Article 32.4 | The repositories system shall include the application programming interfaces allowing wholesalers or persons authorised or entitled to supply medicinal products to the public to query the repositories system by means of software, for the purposes of verifying the authenticity of the unique identifiers and of decommissioning them in the repositories system. The application programming interfaces shall also allow national competent authorities to access the repositories system by means of software, in accordance with Article 39.<br><br>The repositories system shall also include graphical user interfaces providing direct access to the repositories system in accordance with Article 35(1)(i). | Provide details to demonstrate compliance with these provisions (for example in internal procedures and user manuals including for instance screenshots, template documents).<br><br>In the event of non-compliance, provide specific details of the issues encountered, impact assessment and target timelines for resolution. |

| **Uploading of information in the repositories system** | | |
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| Article 33.2 | For a medicinal product bearing a unique identifier, at least the following information shall be uploaded to the repositories system:<br><br>(a) the data elements of the unique identifier in accordance with Article 4(b);<br><br>(b) the coding scheme of the product code;<br><br>(c) the name and the common name of the medicinal product, the pharmaceutical form, the strength, the pack type and the pack size of the medicinal product, in accordance with the terminology referred to in Article 25(1)(b) and (e) to (g) of the Commission Implementing Regulation (EU) No 520/2012;<br><br>(d) the Member State or Member States where the medicinal product is intended to be placed on the market;<br><br>(e) where applicable, the code identifying the entry corresponding to the medicinal product bearing the unique identifier in the database referred to in Article 57(1)(l) of Regulation (EC) No 726/2004 of the European Parliament and the Council;<br><br>(f) the name and address of the manufacturer placing the safety features;<br><br>(g) the name and address of the marketing authorisation holder;<br><br>(h) a list of wholesalers who are designated by the marketing authorisation holder, by means of a written contract, to store and distribute the products covered by his marketing authorisation on his behalf. | Is the information (a) – (h) uploaded through the hub or through the national/supranational system?<br><br>Is this data stored in the repository system after upload and is it accessible to all parties required to verify the authenticity of products?<br><br>Is all the information correctly uploaded and available?<br><br>Are the data elements of the unique identifier uploaded in accordance with Article 4(b) and as determined by national legislation? |
| Article 33.3 | The information referred to in Article 33.2 shall be uploaded to the repositories system either through the hub or through a national or supranational repository. | If data upload is through the national/supranational repository, is a copy of the information referred to in (a) – (d) above, with the exception of the serial number, immediately transferred to the hub and was this functionality tested and found to be compliant? |

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| | Where the upload is performed through a national or supranational repository, that repository shall immediately transfer to the hub a copy of the information referred to in paragraph 2(a) to (d), with the exception of the serial number, using the data format and data exchange specifications defined by the hub. | In the event of non-compliance, provide specific details of the issues encountered, impact assessment and target timelines for resolution. |
| Article 33.4 | The information referred to in paragraph 2 shall be stored in the repositories where it was originally uploaded for at least one year after the expiry date of the medicinal product or five years after the product has been released for sale or distribution in accordance with Article 51(3) of Directive 2001/83/EC, whichever is the longer period. | Has the system been configured to meet this provision?<br><br>How is data securely deleted/archived? |
| **Functioning of the hub** | | |
| Article 34.2 | When the authenticity of the unique identifier cannot be verified because a national or supranational repository does not contain a unique identifier with the product code and serial number that are identical to those of the unique identifier being verified, the national or supranational repository shall transfer the query to the hub in order to verify whether that unique identifier is stored elsewhere in the repositories system.<br><br>When the hub receives the query, the hub shall identify, on the basis of the information contained therein, all national or supranational repositories serving the territory of the Member State or Member States where the medicinal product bearing the unique identifier was intended to be placed on the market, and shall transfer the query to those repositories.<br><br>The hub shall subsequently transfer the reply of those repositories to the repository which initiated the query. | Has this been tested and found to be compliant?<br><br>In the event of non-compliance, provide specific details of the issues encountered, impact assessment and target timelines for resolution. |
| **Characteristics of the Repository System** | | |
| Article 35.1 | Each repository in the repositories system shall satisfy all of the following conditions:<br><br>(a) it shall be physically located in the Union; | Provide the relevant details to verify compliance with (a) – (i) |

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| | (b) it shall be set up and managed by a non-profit legal entity established in the Union by manufacturers and marketing authorisation holders of medicinal products bearing the safety features and, where they have chosen to participate, wholesalers and persons authorised or entitled to supply medicinal products to the public;<br><br>(c) it shall be fully interoperable with the other repositories composing the repositories system; for the purposes of this Chapter, interoperability means the full functional integration of, and electronic data exchange between repositories regardless of the service provider used;<br><br>(d) it shall allow the reliable electronic identification and authentication of individual packs of medicinal products by manufacturers, wholesalers and persons authorised or entitled to supply medicinal products to the public, in accordance with the requirements of this Regulation;<br><br>(e) it shall have application programming interfaces able to transfer and exchange data with the software used by wholesalers, persons authorised or entitled to supply medicinal products to the public and, where applicable, national competent authorities;<br><br>(f) when wholesalers and persons authorised or entitled to supply medicinal products to the public query the repository for the purposes of verification of authenticity and decommissioning of a unique identifier, the response time of the repository, not considering the speed of the internet connection, shall be lower than 300 milliseconds in at least 95 % of queries. The repository performance shall allow wholesalers and persons authorised or entitled to supply medicinal products to the public to operate without significant delay;<br><br>(g) it shall maintain a complete record ('audit trail') of all operations concerning a unique identifier, of the users performing those operations and the nature of the operations; the audit trail shall be created when the unique | In relation to Article 35.1(c) provide test records proving interoperability between the different repositories and provide details in relation to how this was tested?<br><br>In the event of non-compliance, provide specific details of the issues encountered, impact assessment and target timelines for resolution.<br><br>In relation to Article 35.1 (h):<br>How is the following guaranteed in the repository:-<br>• the protection of personal data?<br>• the protection of information of a commercially confidential nature?<br>• the ownership and confidentiality of the data generated when users interact with it?<br><br>In relation to Article 35.1 (g-h): safeguarding confidentiality and protection of personal data while accessing metadata and generating audit-trail reports is crucial:<br><br>• What measures are in place/actions taken to prevent access to audit trail reports by non-NCA personnel?<br><br>In relation to personnel contracts, the following could be considered:<br>• Confidentiality clause in the contract of all personnel with potential access to data and metadata (raw and processed) or reports, collecting information on potential conflict of interest, training on confidentiality to incoming personnel etc. |

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| | identifier is uploaded to the repository and be maintained until at least one year after the expiry date of the medicinal product bearing the unique identifier or five years after the product has been released for sale or distribution in accordance with Article 51(3) of Directive 2001/83/EC, whichever is the longer period;<br><br>(h) in accordance with Article 38, its structure shall be such as to guarantee the protection of personal data and information of a commercially confidential nature and the ownership and confidentiality of the data generated when manufacturers, marketing authorisation holders, wholesalers and persons authorised or entitled to supply medicinal products to the public interact with it;<br><br>(i) it shall include graphical user interfaces providing direct access to it to the following users verified in accordance with Article 37(b):<br>(i) wholesalers and persons authorised or entitled to supply medicinal products to the public, for the purposes of verifying the authenticity of the unique identifier and decommissioning it in case of failure of their own software;<br><br>(ii) national competent authorities, for the purposes referred to in Article 39; | Is such a clause included in personnel contracts?<br><br>Is there an SOP in place for these personnel to follow, if they access the raw data or metadata?<br><br>Is there a listing of personnel in place that has this access? |
| Article 35.2 | Where the status of a unique identifier on a medicinal product intended to be placed on the market in more than one Member State changes in a national or supranational repository, that repository shall immediately notify the change of status to the hub, except in case of decommissioning by marketing authorisation holders in accordance with Articles 40 or 41. | Has this been tested and found to be compliant?<br><br>In the event of non-compliance, provide specific details of the issues encountered, impact assessment and target timelines for resolution. |
| Article 35.3 | National or supranational repositories shall not allow the upload or storage of a unique identifier containing the same product code and serial number as another unique identifier already stored therein. | Has this been tested and found to be compliant?<br><br>In the event of non-compliance, provide specific details of the issues encountered, impact assessment and target timelines for resolution. |

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| **Operations of the repositories system** | | |
| Article 36 | The repositories system shall provide for at least the following operations:<br>(a) the repeated verification of the authenticity of an active unique identifier in accordance with Article 11;<br><br>(b) the triggering of an alert in the system and in the terminal where the verification of the authenticity of a unique identifier is taking place when such verification fails to confirm that the unique identifier is authentic in accordance with Article 11. Such an event shall be flagged in the system as a potential incident of falsification except where the product is indicated in the system as recalled, withdrawn or intended for destruction;<br><br>(c) the decommissioning of a unique identifier in accordance with the requirements of this Regulation;<br><br>(d) the combined operations of identification of a pack of a medicinal product bearing a unique identifier and verification of the authenticity and decommissioning of that unique identifier;<br><br>(e) the identification of a pack of a medicinal product bearing a unique identifier and the verification of the authenticity and the decommissioning of that unique identifier in a Member State which is not the Member State where the medicinal product bearing that unique identifier was placed on the market;<br><br>(f) the reading of the information contained in the two-dimensional barcode encoding the unique identifier, the identification of the medicinal product carrying the barcode and the verification of the status of the unique identifier, without triggering the alert referred to in point (b) of this Article; | Provide the relevant details to verify compliance with (a) – (o).<br><br>In the event of non-compliance, provide specific details of the issues encountered, impact assessment and target timelines for resolution.<br><br>In relation to 36 (b):<br>• What alert is displayed in the system when a pack cannot be authenticated? Provide reference to relevant procedure for alerts and their investigation (*exception: where the product is indicated in the system as Recalled, Withdrawn or intended for Destruction*)<br>• How is this event flagged in the system, e.g. push alert to NMVO, pull alert through reporting, etc.?<br><br>In relation to 36 (g):<br>• How is this access achieved?<br><br>In relation to 36 (i):<br>• Can any information on a given UI immediately be provided to the NCA/EMA upon request?<br><br>In relation to 36 (l):<br>• How is it indicated to a user that a UI has been decommissioned?<br><br>In relation to 36 (m):<br>How is it indicated that a product has been:- |

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| | (g) without prejudice to Article 35(1)(h), the access by verified wholesalers to the list of wholesalers referred to in Article 33(2)(h) for the purposes of determining whether they have to verify the unique identifier of a given medicinal product.<br><br>(h) the verification of the authenticity of a unique identifier and its decommissioning by manually querying the system with the data elements of the unique identifier;<br><br>(i) the immediate provision of information concerning a given unique identifier to the national competent authorities and the European Medicines Agency, upon request;<br><br>(j) the creation of reports that allow competent authorities to verify compliance of individual marketing authorisation holders, manufacturers, wholesalers and persons authorised or entitled to supply medicinal products to the public with the requirements of this Regulation or to investigate potential incidents of falsification;<br><br>(k) the reverting of the status of a unique identifier from decommissioned to active, subject to the conditions referred to in Article 13;<br><br>(l) the indication that a unique identifier has been decommissioned;<br><br>(m) the indication that a medicinal product has been recalled, withdrawn, stolen, exported, requested as a sample by national competent authorities, indicated as a free sample by the marketing authorisation holder, or is intended for destruction;<br><br>(n) the linking, by batches of medicinal products, of the information on unique identifiers removed or covered to the information on the equivalent unique identifiers placed on those medicinal products for the purposes of complying with Article 47a of Directive 2001/83/EC. | • recalled<br>• withdrawn<br>• stolen<br>• exported<br>• requested as a sample by NCA<br>• indicated as a free sample by the MAH<br>• intended for destruction |

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| | (o) the synchronisation of the status of a unique identifier between the national or supranational repositories serving the territory of the Member States where that medicinal product is intended to be placed on the market. | |
| **Obligations of legal entities establishing and managing a repository which is part of the repositories system** | | |
| Article 37 | Any legal entity establishing and managing a repository which is part of the repositories system shall perform the following actions: | |
| | (a) inform the relevant national competent authorities of its intention to physically locate the repository or part of it in their territory and notify them once the repository becomes operational; | Provide records. |
| | (b) put in place security procedures ensuring that only users whose identity, role and legitimacy has been verified can access the repository or upload the information referred to in Article 33(2); | Provide reference to relevant procedures. |
| | (c) continuously monitor the repository for events alerting to potential incidents of falsification in accordance to Article 36(b);<br><br>&<br><br>(d) provide for the immediate investigation of all potential incidents of falsification flagged in the system in accordance with Article 36(b) and for the alerting of national competent authorities, the European Medicines Agency and the Commission should the falsification be confirmed; | Provide reference to relevant procedures including details as to who gets notified and how/by what means?<br><br>Provide a process flow diagram for investigation of potential incidents of falsification flagged in the system including the subsequent escalation/notification stages to the relevant competent authorities. |
| | (e) carry out regular audits of the repository to verify compliance with the requirements of this Regulation. Audits shall take place at least annually for the first five years after this Regulation becomes applicable in the Member State where the repository is physically located, and at least every three years thereafter. The outcome of those audits shall be provided to competent authorities upon request; | Provide reference to relevant procedures for internal audits and resolving CAPAs and complaints.<br><br>Who is authorised to perform internal audits and how is confidentiality of data and information safeguarded during such audits?<br><br>How is Article 38.2 taken into account when providing auditors with access to data for the audit? |

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| | | Provide a copy of the audit schedule and indicate the scope of such audits. |
| | (f) make the audit trail referred to in Article 35(1)(g) immediately available to competent authorities upon their request; | Is this audit trail available? See 35.1. about confidentiality.<br><br>In the event of non-compliance, provide specific details of the issues encountered, impact assessment and target timelines for resolution. |
| | (g) make the reports referred to in Article 36(j) available to competent authorities upon their request. | Provide confirmation as to whether the agreed reports are accessible to competent authorities?<br><br>In the event of non-compliance, provide specific details of the issues encountered, impact assessment and target timelines for resolution. |
| **Data protection and data ownership** | | |
| Article 38.2 | The legal entity managing the repository where the audit trail is stored shall not access the audit trail and the data contained therein without the written agreement of the legitimate data owners except for the purpose of investigating potential incidents of falsification flagged in the system in accordance with Article 36(b). | Is the audit trail and the data contained therein only accessed by the NMVO following written agreement of the legitimate data owners?<br>(*Exception: for the purpose of investigation of potential incidents of falsification flagged in the system*) |

| **Part II: Quality Management System (QMS)** | **NMVO Response.**<br>**Reference to relevant procedures should be provided, where applicable.** |
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| The quality system is defined | Provide a high level overview of the quality system implemented and a listing of key procedures and forms/templates controlled under the QMS. |
| The quality manual covers all elements of the defined quality system | |
| The quality system has been implemented and is followed | |
| A documentation control/management system is in place | |
| A procedure for evaluation of the bona fides/qualification of end users (wholesalers, persons entitled to supply medicinal products to the public, e.g. pharmacies, hospitals) prior to granting access to the repository is implemented.<br><br>A procedure for subsequent periodic review of the bona fides to identify any operator who has had its authorisation/licence revoked/suspended and instructions for the disabling of the repository access for concerned operators. | |
| A process/procedure is implemented for Management of Incidents/Potential Incidents of Falsification | |
| A process/procedure for Change Management is implemented | |
| A process/procedure for managing Complaints is implemented | |
| A process/procedure for Risk Management is implemented/Life Cycle of Repository System | |
| A process/procedure for Information Security Management is implemented<br><br>Has an IT security audit of the system been conducted? | |
| A process/procedure for CAPA Management is implemented | |
| A process/procedure for System Access Management is implemented | |
| A process/procedure for Training is implemented | |
| Business Continuity | |

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| Risk Assessment<br>Process/Procedure implemented<br>Is there an alternative system in the event of repository breakdown? Have these arrangements been documented and tested?<br>How is database size/growth managed?<br>How is system performance managed?<br>How is system interruption mitigated? How does this impact the User's System? | |

| **Part III: NMVO Organisation/NMVS** | **NMVO Response** |
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| Organisation Structure/Organogram including functional and hierarchical reporting lines<br>Members<br>Board of Directors<br>Roles & Responsibilities and deputizing<br><br>Arrangements/procedures related to management of impartiality and conflict of interest. | Provide details. |
| NMVS Service Provider<br><br>NMVS – Blueprint, Customised Blueprint or Bespoke System | Provide details |
| Contract between NMVO & NMVS Service Provider | Indicate if a contract is in place, provide reference to contract and duration of contract. |
| Contract between NMVO & EMVO | Indicate if a contract is in place, provide reference to contract and duration of contract. |
| Contracts between NMVO & End User IT Software Providers | Indicate if contracts are in place, provide references to contracts and duration of contracts. |