

## **Guideline for Member States Supervision of the National Medicines Verification Systems/National Medicines Verification Organisations**

### **Scope**

The purpose of this document is to provide guidance for supervision of the National Medicines Verification Systems/National Medicines Verification Organisations to enable a harmonised approach regarding application of the rules as set out in Article 44 of Commission Delegated Regulation (EU) 2016/161 of the 2 October 2015.

The supervision activities are required to verify that the repositories and the legal entities responsible for the establishment and management of the repositories comply with the requirements of this Regulation.

### **Introduction**

The National Medicines Verification Organisations (NMVOs) are non-profit legal entities established in Member States, responsible for the set up and management of the National Medicines Verification Systems (NMVSs). The NMVOs represent stakeholders in the medicines supply chain across the European Union (EU) Marketing Authorisation Holders, manufacturers, wholesaler's etc.

### **Legislative Basis**

Directive 2011/62/EU of the European Parliament and of the Council of the 8 June 2011 amended 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.

Directive 2011/62/EU included a provision for the Commission to adopt, by means of delegated acts in accordance with Article 121a and subject to the conditions laid down in Articles 121b and 121c, measures supplementing point (o) of Article 54 with the objective of establishing the detailed rules for the safety features referred to in point (o) of Article 54.

The European Commission Delegated Regulation (EU) 2016/161 for Safety Features on Medicinal Products for Human Use that supplements Directive 2001/83/EC, with detailed rules for the safety features appearing on the packaging of medicinal products for human use was published in the Official Journal of the European Union on the 9 February 2016. The Delegated Regulation will apply in all Member States, with the exception of Belgium, Greece and Italy, from the 9 February 2019.

At the time of entry into force of Directive 2011/62/EU, Belgium, Greece and Italy already had systems in place for the verification of the authenticity of medicinal products and for the identification of individual packs. Directive 2011/62/EU granted such Member States an additional transitional period for adapting to the harmonised Union system for safety features.

The Delegated Regulation shall be applied in these Member States at the latest from the 9 February 2025. Belgium has formally renounced using this extension and confirmed the application of the new rules as of the 9 February 2019.

### **Procedure**

The EU national competent authority responsible for the supervision of the NMVS/NMVO is the competent authority of the Member State in which the NMVS/NMVO is physically located. It is understood that inspections will take place at the premises of the NMVO legal entity, as opposed to the

site at which the system infrastructure (the repository) e.g. servers may be physically located, where different.

However, in the case where an EU national competent authority requires to inspect the repository used for the purpose of verifying the authenticity of medicinal products placed on the market and where that repository is not physically located in the territory of that Member State, the national competent authority of that Member State may observe an inspection of the NMVS/NMVO or perform an independent inspection, subject to the agreement of the national competent authority in the Member State in which the NMVS/NMVO is physically located, in accordance with Article 44 (3).

The national competent authority may delegate any of its obligations under Article 44 to the competent authority of another Member State or to a third party, by means of a written contract, in accordance with Article 44 (2).

The national competent authority shall communicate reports of supervision activities to the European Medicines Agency (EMA), which shall make them available to the other national competent authorities and the Commission, in accordance with Article 44 (4). The reports should be provided to the EMA in the English language and may be redacted to exclude any information of personal, confidential or commercially sensitive nature.

The EMA will upload the reports to its "MMD" system from which they may be accessed by national competent authorities.

### Inspections

The supervision activities may involve on-site based inspections at the premises of the NMVO/NMVS and/or remote desk-top based inspections. Inspection reports should clearly indicate whether the inspection was on-site or remote.

The inspection frequency will be risk based taking a number of criteria into account, e.g. time period since establishment (i.e. more frequent inspections may occur initially), whether the previous inspection was on-site or remote, compliance rating following inspection\*, complexity of the organisation/repository (i.e. national vs. supranational), following the notification of compliance or other issues from EU Member States or from stakeholders etc.

An *Assessment Questionnaire* (for completion by NMVOs) and an *Aide Memoire for Inspection* are available to national competent authorities as separate documents.

\*Compliance rating following inspection will be dependent on the overall compliance of the NMVO/NMVS with the requirements of the Delegated Regulation.

Compliance ratings may be defined as follows:

- Compliant - NMVO operational with no observations. Recommendations can be made for the rating to be given.
- Compliant with observations - NMVO operational with observations but none that adversely impact the daily operation of the NMVO.
- Non - Compliant – NMVO with observations that adversely impact the daily operation of the service provided.
- Not Operational – NMVO has subjected itself to voluntary inspection prior to the go live date, observations and recommendations may be made but do not give rise to a compliance rating.

### Quality System Standards

Aspects of many existing Standards may be applicable for NMVO/NMVS inspections. The systems installed should be robust and should deliver on the requirements of the Delegated Regulation and relevant procedures should be in place in relation to governance and management.

Validation of the systems should demonstrate through testing that they are fit for purpose and GMP/Pharmaceutical industry models may be used in this regard.

In addition to the requirements specified in Directive 2011/62/EU and the Delegated Regulation (EU) 2016/161, the following is a non-exhaustive list of other relevant standards that may be applied:-

- EU GMP Annex 11: Computerised systems
- EU GMP Annex 15: Qualification and Validation
- GAMP® 5: A Risk-Based Approach to Compliant GxP Computerised Systems
- PIC/S Guidance: Good Practices For Computerised Systems In Regulated “GXP” Environments, PI 011-3
- ISO/IEC 27001: 2013 Information security management systems
- ISO/IEC 27002: 2013 Code of practice for information security controls
- ISO/IEC 27005: Information security risk management
- ISO/IEC 38500: Governance of IT for the organisation
- ISO/IEC 20000: IT service management