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Joint Ministerial Decision on the establishment of the 'Hellenic Medicines Verification Organization'

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On December 31, 2020, **Joint Ministerial Decision ('JMD')** D3 (a) 41169/19 (OGG B' 6124/31.12.2020) was issued by the Minister of Development and Investments and the Minister of Health. The JMD provides for the establishment of the **'Hellenic Medicines Verification Organisation' ('HMVO'),** i.e. a non – profit legal entity aiming at the formation and management of the '**Hellenic Medicines Verification System' ('HMVS')** for medicinal products for human use bearing the safety features in accordance with the **Delegated Regulation (EU) 2016/161 ('Delegated Regulation')** «supplementing **Directive 2001/83/EC ('Directive')** by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use». HMVS, as a National Medicines Verification System (NMVS), mainly constitutes the verification platform that pharmacies or other registered parties (wholesalers, hospital pharmacies etc.) use to verify the authenticity of a product. In particular, it is the repository containing the information uploaded by the manufacturers and the MAHs on the safety features enabling the verification of authenticity and the identification of medicinal products bearing the safety features, under the law, and enabling wholesalers, pharmacists and any person entitled to supply medicinal products to the public to verify the information referred to in article 77 par. ιε of JMD 32221/2013[1].

On the basis of art. 32 of the Delegated Regulation, the structure of the repositories' system is set out. It shall be composed of a central information and data router (the European Hub) and repositories which serve the territory of one or multiple Member States and will be connected to the EU-Hub. Therefore, each European country (EU, EEA and Switzerland) has to implement a NMVS which will be managed by a National Medicines Verification Organisation (NMVO).

Products that are in scope of the JMD are: a) the medicinal products subject to prescription which shall bear safety features on their packaging, as referred to in article 77 par. ιε of JMD 32221/2013, unless included in the European Commission's negative list, b) medicinal products not subject to prescription included in the European Commission's positive list, as well as the medicinal products to which EOF have extended the scope of application of the unique identifier, per article 2 paragraph (1) (c) of the DR.

The JMD determines the following for the establishment of the HMVO:

[1] JMD ΔΥΓ3α/32221/2013 (OGG B' 1049).

Legally obliged persons for the establishment of HMVO

Manufacturers and Marketing Authorisation Holders (MAHs) of medicinal products for human use bearing the safety features are legally obliged to set up and manage the HMVO. The above mentioned persons are entitled to participate in the HMVO through their representatives.

Structure

According to the JMD the HMVO;

- is part of the **'European Medicines Verification Organisation' ('EMVO')**[2];
- constitutes a legal **non – profit entity with no insolvency capacity**;
- takes the form of **civil law non – profit partnership** or **association of civil code** under the name **'Hellenic Medicines Verification Organisation' ('HMVO')**;
- has its **seat** in Athens;
- **is not be part of the public sector or the wider public sector**;
- shall **not exercise disciplinary authority** over its members **nor public power**;
- bear **civil and criminal liability** for any violation of the provisions of JMD 32221/2013, the DR, and the provisions of pharmaceutical's legislation that fall under its scope.

[2] EMVO is a non – profit organization ensuring the implementation of a medicines verification system across Europe and responsible for the formation of the European Medicines Verification System (EMVS), i.e. the European repositories system, that constitutes the central information and control hub.

Operation, Management, Minimum Content of Statute

- HMVO's purpose shall be the formation, operation and management of the '**Hellenic Medicines Verification System' ('HMVS')**;
- HMVO's purpose, rights and obligations laid down in statute shall be in accordance with the DR and the JMD;
- HMVO shall be governed by a collegiate body composed of its members or representatives of its representative bodies;
- the cost of establishment and operation of HMVO shall be borne by the manufacturers and the MAHs of medicinal products bearing the safety features;

In that vein, participation to the HMVO is **mandatory** for the following persons:

- Manufacturers authorised in Greece to supply medicinal products for human use;
- MAHs of medicinal products for human use bearing the safety features in Greece including any designated local representatives;
- Any person responsible for the holding and distribution of medicinal products bearing an equivalent unique identifier for the purposes of complying with article 47a of Directive (e.g. parallel importer) that shall ensure that the information referred to in paragraph 2 of article 33 of the DR are uploaded to the repositories system before the medicinal product is released for sale or distribution by

the manufacturer, and that it is kept up to date thereafter;

- Any fiscal or legal person authorised to hold and distribute medicinal products, by virtue of article 29 of Law 1316/1983.

To that end, the statute foresees flexible ways of admission, resignation and participation in general for the aforementioned legally obliged persons.

Additionally, the statute shall provide for the participation of wholesalers and pharmacists[3] pursuant to article 31 paragraphs (3) and (4) of the DR.

The use of the HMVS is mandatory to all persons active in medicinal products' supply chain, e.g. in the production and distribution up to the end consumer.

Sanctions

HMVO makes available to the national competent authority (EOF), at any time, the data contained in the HMVS.

Except for the sanctions provided in other provisions of the applicable legislation, especially article 19 of Legislative Decree ('LD') 96/1973, the sanctions of article 12 par. 4 of LD 96/1973 shall apply for offenses of the JMD's provisions.

In case of shortage of a medicinal product due to JMD violation, the sanctions provided for in article 12A paragraph 1 of LD 96/1973, shall be imposed.

Next steps

Within three months from the entry into force of the JMD, the HMVO's statute will be subject to the procedures for its legal establishment laid down in the law. Once it becomes operational, HMVO shall inform EOF, as the competent authority for DR's enforcement and HMVO's supervisory authority.

[3] The notions 'pharmacist' and 'pharmacy' include any structure entitled to supply medicinal products to the public, such as hospitals (private and public), EOPYY pharmacies, as well as any other entity entitled to supply medicinal products to the public.

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