Healthcare, Pharma and Life Sciences newsletter

New Ministerial Decision 6030/2025 | Key Changes in Pharmaceutical Regulations

The proliferation of counterfeit medicines across the European Union is a major concern for public health. These fraudulent products, which alarmingly penetrate the market not only through illicit channels but also through legitimate supply chains, are often identified by inaccurate packaging, misleading labels, incorrect ingredients, and sometimes fabricated distribution records.

To address the foregoing health risks across the EU market, the EU released the "COMMISSION DELEGATED REGULATION (EU) 2016/161 of 2 October 2015" which describes a system, which allows for an "end-to-end" verification of medical products bearing the safety features by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use.

At a national level, Ministerial Decision Δ3(α) 6030 (Government Gazette (FEK) 407 Issue B' 07.02.2025) has been introduced providing for the amendment of Ministerial Decision 32221/2013, the latter constituting the main legislative piece governing the manufacturing and circulation of medicinal products in Greece. The provisions of the new Ministerial Decision, effective as from 9 February 2025, are intended, inter alia, to enhance safety measures to ensure conformity with EU standards in this respect. At the local level, the new two-dimensional barcode (2D Barcode) will replace the EOF authenticity label and the reimbursement process will be completed simultaneously with the product's decommissioning.

The key amendments can be summarised as follows.

Mandatory Safety Features on Medicinal Products

i. **Prescription medicines** must now bear safety features, unless explicitly exempted by EU catalogs.
ii. **OTC medicines** are generally exempt, except those identified as high-risk for falsification.
iii. **Reimbursed medicines**, whether prescription or OTC, must include safety features.

New Labeling Requirements

i. The obligation to display product pricing on packaging has been abolished.
ii. Medicines must clearly indicate their prescription status and include a recycling mark on the outer packaging.
iii. OTC medicines must now feature the EOF Unique Code (National Medicinal Product Identification Number) in both barcode and human-readable format.

Special Labeling for Institutional Use

i. Medicines supplied to public hospitals and institutions must be labeled "STATE PRODUCT" («ΚΡΑΤΙΚΟ ΕΙΔΟΣ»).
ii. Products distributed within private clinic pharmacies must be marked "PRIVATE CLINIC PHARMACY" («ΦΑΡΜΑΚΕΙΟ ΙΔ. ΚΛΙΝΙΚΗΣ»).

Stricter Rules on Repackaging & Safety Features Replacement

i. Repackaging is allowed only under strict conditions. Before removing or covering existing safety features, the Marketing Authorisation Holder (MAH) must verify the product's authenticity under the National Organisation for Medicines' (EOF) supervision.
ii. If safety features are replaced, the new ones must comply with EU regulations and offer equivalent protection against falsification.

Enhanced Market Monitoring & Compliance Checks

i. EOF will continue risk assessments and market surveillance in collaboration with the Hellenic Medicines Verification Organisation (HMVO) to prevent falsified medicines from entering the supply chain which is achieved through the Hellenic Medicines Verification System (HMVS). This system is instrumental in identifying risks related to counterfeit medicines, ensuring regulatory compliance, and bolstering pharmacovigilance initiatives.

ii. Moreover, EOF will carry out risk evaluations aimed at preventing falsification, taking into account various elements such as the product's cost, sales figures, historical instances of falsification, the seriousness of the diseases addressed, and possible risks to public health. These assessments will assist in identifying which products necessitate enhanced safety protocols.

Obligations imposed to Wholesalers

i. **Supply Restrictions:** Wholesalers are required to supply pharmaceutical products only to individuals or entities that possess a wholesale distribution licence or are authorised to supply medicines to the public, in accordance with existing regulations.

ii. **Verification of Authenticity:** Wholesalers must verify that the medicines they receive are not counterfeit. This entails verifying the safety features present on the external packaging of the products, in accordance with the provisions set forth in Regulation (EU) 2016/161 and the stipulations outlined in Articles 77 and 78 of Ministerial Decision 32221/2013.

iii. **Decommissioning of Unique Identifiers:** Before supplying medicines to entities specified in Article 23 of Regulation (EU) 2016/161, wholesalers must verify the safety features and decommission the unique identification number of the medicines.

iv. **Verification for Non-Safety Feature Medicines:** Wholesalers are also obligated to verify that medicines which do not fall under the safety feature system are not counterfeit, in accordance with the requirements of articles 77 and 78 of Ministerial Decision 32221/2013.

Sanctions for Non-Adherence

The possession of medicinal products featuring decommissioned safety mechanisms is strictly forbidden for all entities involved in the pharmaceutical supply chain, except where expressly authorised by law. Those found in violation of this prohibition may incur fines reaching EUR 44,000. Additionally, EOF retains, at its discretion, the authority to seize any medicinal products that do not comply with these regulations.

EOF Circular No. 21036/20.02.2025

In response to the aforementioned obligations, EOF has recently issued Circular No. 21036/20.02.2025 to implement Ministerial Decision Δ3(α) 6030/2025, aligning Greek pharmaceutical regulations with EU standards to combat falsified medicines and enhance supply chain transparency.

A key provision of the above circular is the introduction of an electronic system, effective as from 27 February 2025, accessible via EOF's online portal. This system enables real-time submission and monitoring of data related to intra-EU distribution and exports of medicinal products. Under this new framework, wholesalers engaged in such transactions are required to submit specific details before proceeding with distribution, including the National Medicinal Product Identification Number (barcode), quantity in packaging units, batch number, batch expiration date, and destination country. Essentially, the system shall notify if the barcode is not recognised during scanning and a protocol for investigation shall follow, which includes the location, the manufacturer, the National Medicines Agency (EMEA), the HMVO and the European Medicines Verification Agency (EMVO).

Additionally, this circular reinforces obligations regarding authenticity labels. For medicinal products that still bear an authenticity label and are intended for intra-EU distribution or export, existing provisions on authenticity labels remain in force, including the requirement to decommission their serial numbering. However, for packaging that includes both safety features and an authenticity label, only the authenticity label must be deactivated in EOF's system, ensuring compliance with traceability regulations.

EOF Clarification Circular No. 30784/13.03.2025

To further clarify the implementation of new safety features for medicines, EOF issued Circular No. 30784/13.03.2025. This circular provides detailed guidance on transitioning from the previous authenticity label system to the new system with unique identifiers and anti-tampering devices, in compliance with EU regulations.

Unique Identifier (UI)

The UI includes a product code, serial number, batch number, and expiration date. These details are presented in a 2D barcode and in a human-readable format on the packaging.

Anti-Tampering Device (ATD)

An ATD (such as a seal, tape or other special way of sealing) is required to verify if the packaging has been tampered with, ensuring the integrity of the medicinal product.

Verification Process

Manufacturers, wholesalers, and authorised entities must verify the authenticity of the UI and the integrity of the ATD throughout the supply chain.

Transition Period

The transition from the authenticity label system to the new safety features system will be completed by 9 February 2025. However, EOF will continue to issue authenticity labels until 7 February 2026, for specific cases, in order to ensure a smooth transition, as follows:

- Medicines released before 9 February 2025
- Authenticity labels will be issued for batches of medicines that were released before 9 February 2025 and are still circulating in the Greek market.
- Prescription Medicines listed in Annex I of the Regulation
- Prescription medicines that are listed in Annex I of the Regulation and are considered low-risk for falsification will continue to receive authenticity labels for reimbursement purposes. This extension is provided to allow sufficient time for the addition of safety features at the local level.
- Non-Prescription Medicines (OTC)
- Non-prescription medicines (OTCs) that are required to display the EOF Unique Code on their packaging will continue to receive authenticity labels until 8 August 2025. This extension is granted to allow time for the inclusion of the EOF Unique Code in both human-readable format and barcode on the packaging.
- Medicines with Technical Implementation Issues

- Medicines for which the Marketing Authorisation Holders have not been able to implement the new safety features due to specific technical reasons. These cases must be justified individually, and the obligation to serialise the products remains in place.

To align with the above requirements there is a mandatory obligation for all relevant stakeholders in the pharmaceutical supply chain to register with the Hellenic Medicines Verification Organisation (HMVO). This includes pharmaceutical companies (MAHs), wholesalers, pharmacies, public hospitals and institutions, as well as private clinic pharmacies. Detailed instructions for the registration process have been provided per category of stakeholder and are accessible on the HMVO website at https://hmvo.gr. By 9 February 2025 all stakeholders must have in principle completed their registration with the HMVO, although it appears that in practice many of them have not done so, thus leaving room for the possibility of imposition of penalties as per above.

Conclusion

Greece's recent legislative changes introduce significant regulatory reforms aimed at enhancing pharmaceutical safety, market transparency, and compliance with EU standards. By implementing stricter safety features, labeling requirements, and repackaging controls, the new framework strengthens the traceability and authenticity of medicinal products in Greece. These reforms are designed not only to enhance public health safeguards but also to foster a safer and more transparent pharmaceutical environment throughout Greece.

In addition, the new framework reinforces EOF's oversight in monitoring the supply chain, minimising the risk of falsified medicines entering the market.

For pharmaceutical companies, wholesalers, and pharmacies, compliance with these new provisions is critical to ensure uninterrupted market access and avoid potential regulatory penalties. As the regulatory landscape continues to evolve, industry stakeholders must adapt to these new requirements and implement necessary adjustments in their operations. Taking into consideration that the deadlines for implementation and compliance are already in place and/or are very tight, it is imperative for pharmaceutical companies and supply chain stakeholders to take immediate action to achieve full compliance with the newly established standards. Businesses should navigate the complexities of the new framework carefully so as to assess their compliance strategies. It remains to be seen whether the red tape usually involved in the practical implementation of such obligations will act as a brake on rapid compliance.

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