



GREECE & ITALY ON-BOARDING STATUS UPDATE

S. Queirós
M. Matarrelli

UPDATE ON ITALY

- The National Medicines Verification Organization Italy was established on 17 January 2024;
- The President, the Board of Directors and the Board of the Statutory auditors were appointed;
- A General Manager has been appointed and EMVO is expecting further information about the selected GM
- Next steps: setting of NMVO fee model, assignment of the task to the IT provider.
- Italian MVO is *"working on an action plan, including a change to the national legislation which will have to provide for the removal of Bollino from all medicines packs."*

In the meantime, the Italian Ministry of Health maintains ongoing communication with the EU Commission regarding the Italian implementation roadmap."

Massimo Gaiotto
NMVO Italia President

UPDATE ON ITALY

- On February 24th the “Legge di delegazione UE” was published providing certain obligations concerning the implementation of the new system in Italy – see Art.6 herewith:
- *the Government is tasked with issuing, within twelve months, one or more legislative decrees to detail the existing legislation in order to comply with the obligations arising from EU legislation (re: FMD);*
 - *to this end, specific and progressive measures will be adopted to make the unique identifier and the anti-tampering security feature affix on medicine packaging, by **February 9th, 2025**;*
 - *the NMVO-Italy member companies, through a specific agreement, will engage the services of the “Poligrafico dello Stato” for the establishment of the national archive.*
- RFP process was launched to select the IT provider.
- The NMVS will have to be connected to the Italian National Health Platform (NSIS) that will remain in use for reimbursement and market surveillance purposes (among other tasks).

UPDATE ON ITALY

MEMBERSHIPS

Farindustria

Egualia (generic/biosimilar/value added medicines manufacturers)

Federfarma (Pharmacy Owners' National Federation)

Federfarma servizi (Services for Pharmacies)

ADF (wholesalers)

AIP (Parallel Importers) and AIM (Parallel Importers)

Assofarm (Association of Socio-Pharmacies Companies and Services)