

# Countries of interest

- Macedonia, Serbia, Montenegro, Bosnia & Herzegovina, Albania and Kosovo
- The new EU falsified medicines safety features:
  - unique identifier (UI) in the form of 2D data matrix code and
  - anti-tempering deviceare not obligatory in these countries.  
  
(Greece & Italy will postpone serialization until 2025)
- The countries of interest use 1D barcodes.

# Labelling – regional aspects

- **Macedonia** – local language labelling;  
per year allowed import with international labelling:
  - originators: 10.000 packs
  - generics: 5.000 packs
- **Serbia** – local language labelling;  
per year allowed import with international labelling:
  - 10.000 packs

# Labelling – regional aspects

- **Montenegro** – local language labelling;  
allowed use of approved Serbian, BiH & Croatian packs with stamp;  
per year allowed import with international labelling:
  - 5.000 packs
  - EU falsified medicines safety features: no limits
- **Bosnia & Herzegovina** – local language labelling;  
only in the 1st year allowed import with international labelling:
  - 3.000 packs

# Labelling – regional aspects

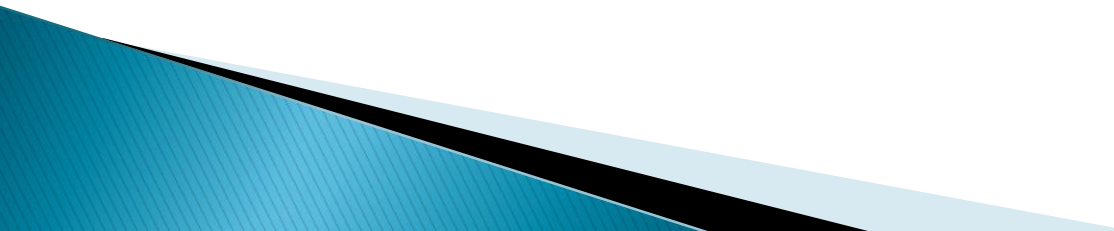
- **Kosovo\*** - local bilingual labelling:
  - Albanian & Serbian;
  - per year allowed import with international labelling:
    - 15.000 packs
- **Albania\*** - local language labelling;
  - possible also to be approved English labelling;
  - not allowed import with international labelling;

\*MAH is manufacturer or foreign MAH

\*Primary packaging can be international

\*Braille is not mandatory

# Global aspects – the future

- **USA** – Unit & Case serialization w/o aggregation, Nov 2017;  
– Serialization traceability, Nov 2023
  - **EU** – Unit level serialization and dispense verification, Feb 2019
  - **Different timelines in different countries** – planned/ongoing/  
implemented serialization
  - **Non-EU countries** – import of serialized packs possible;  
serialization implementation is expected
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# Labelling strategy of Bionika Pharmaceuticals

- **Non-EU countries** – serialization is not needed
  - **OTC medicines** - serialization is not needed
  - **EU Rx medicines** - serialization & batch release will be done by EU contract manufacturer
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