The case of the implementation of the Falsified Medicines Directive in Europe

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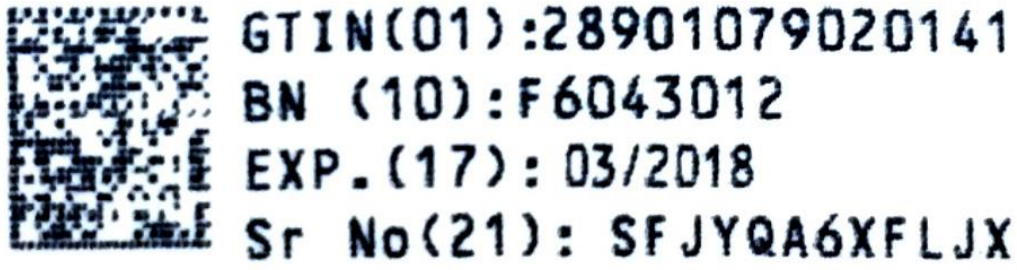
The Delegated Regulation is here

- New technology at the core of preventing illicit trade and counterfeiting
- The dispensing of medicine will change forever
- Patient safety will be significantly improved
- All medicines will need to be ‘checked-in’ and ‘checked-out’ of a repository service

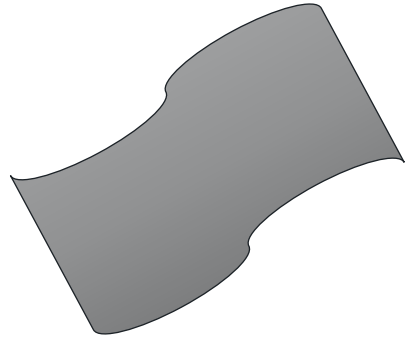
The visible elements– quick recap

1. Generate the codes



2. Print 2D codes on the packs

3. Add and test tamper evident



(i) Product code GTIN (01)
(ii) Batch number BN (10)
(iii) Expiry date EXP. (17)
(iv) Serial number Sr No (21)
(v) Optional reimbursement number

4. Upload the codes to the EU Hub or on the National Repository*)

***) National database structures are not yet deployed in most European countries. EU Hub, certification and integration ongoing.**


Manufacturer
Serialise
Sent to EU Hub
Upload to National repository
Pharmacy/ Wholesaler Software
Medicine Scanned
Authenticate/ Verify in repository
Pharmacy Dispensing Point

Implementing the FMD

- It has to be rolled out, tested and working by February 2019
- That means there is a collective responsibility across the medicines supply chain
- There is no single entity who can make this happen in their own

Impacts on the Supply Chain

For manufacturers

There are challenges:

- Production line changes
- Packaging and re-design durability
- Effective interaction with repositories
- The need for real world testing

For wholesalers

Some of the key issues are:

- Aggregation – not mandatory, time to negotiate with manufacturers
- Decommissioning - for products to be distributed outside of the Union
- Or for products intended for destruction
- Or products returned to the wholesaler by authorised persons or another wholesaler that cannot be returned to saleable stock

For pharmacies

The request are:

- No new software systems
- No delay in serving patients
- No Disruption to work flows
- No Complex training

The Opportunity

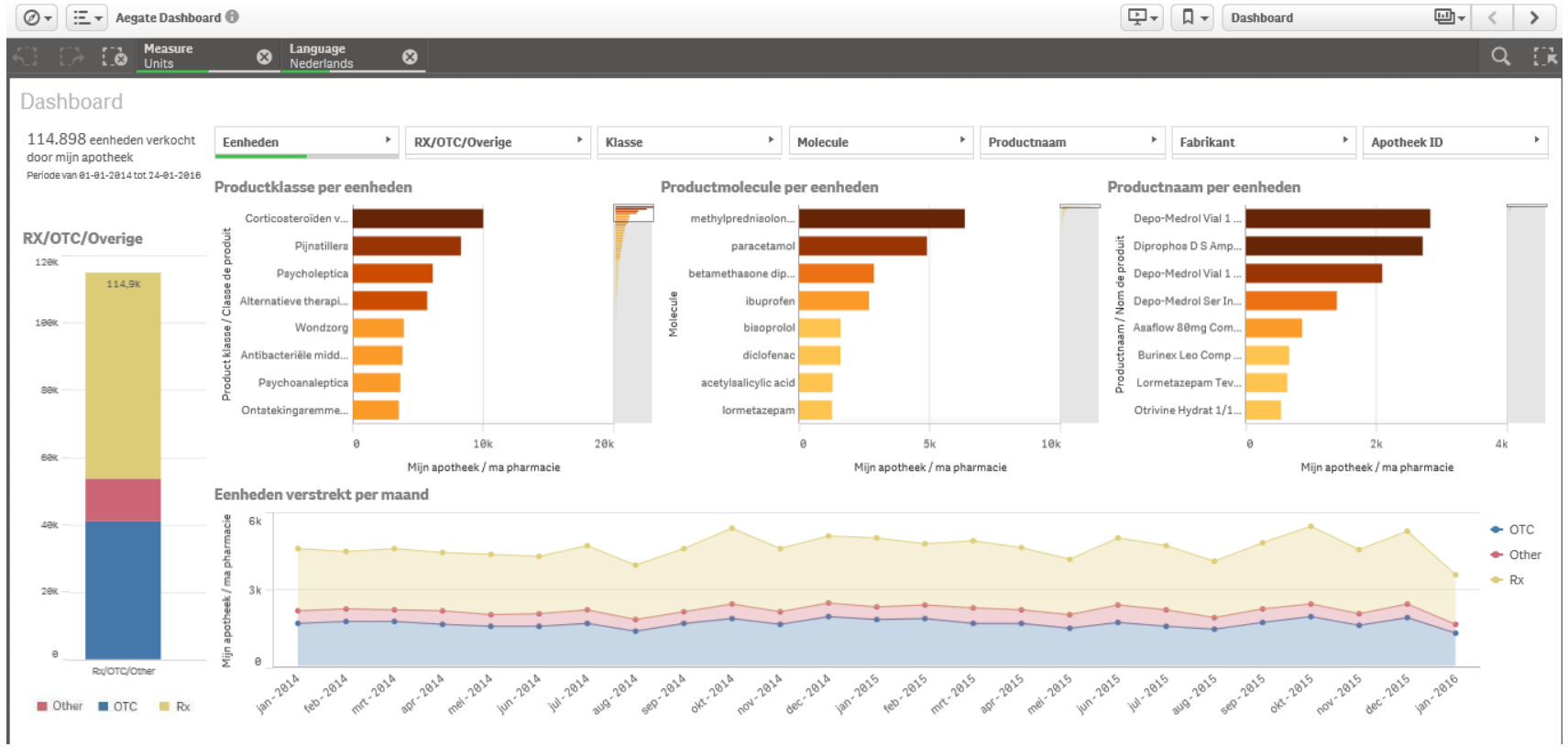
Patient Safety

PLUS

- The opportunity to improve treatment outcomes
- The opportunity to assist pharmacovigilance
- The opportunity to improve stock management and (potentially) cost control

Unique for Belgium

- The Pharmacy Dashboard



Summary

Legislation for a good reason

- Implementing the FMD is not about regulatory box ticking but is totally focused on patient safety

- There are opportunities for all points in the medicine supply chain:

- Brand protection
- Efficient working
- Stock management
- Safer medicines and improved patient outcomes

Legislation for a good reason

- Challenges:

- Cost and time of implementation

- Critical for success: rely and trust on brand owners and whole supply chain

Which lessons can be drown for other sectors? see CAIT white paper