SAFER EUROPE WITHOUT FALSIFIED MEDICINES

European Commission

EU2017.EE Estonian Presidency of the Council of the European Union

Implementation by the Member States- Supervision of repositories

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"Safer Europe without Falsified Medicines"

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Tallin

Health

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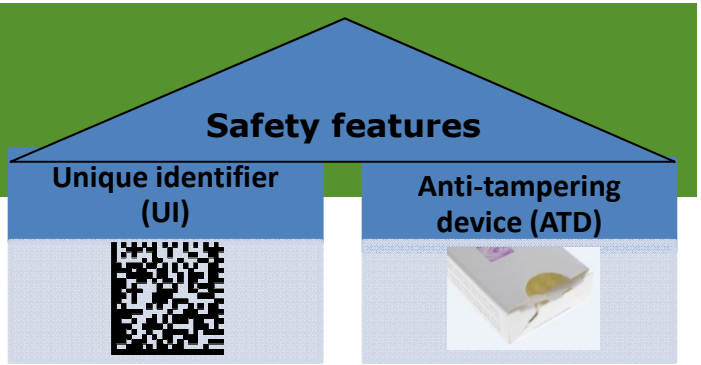
Safety Features

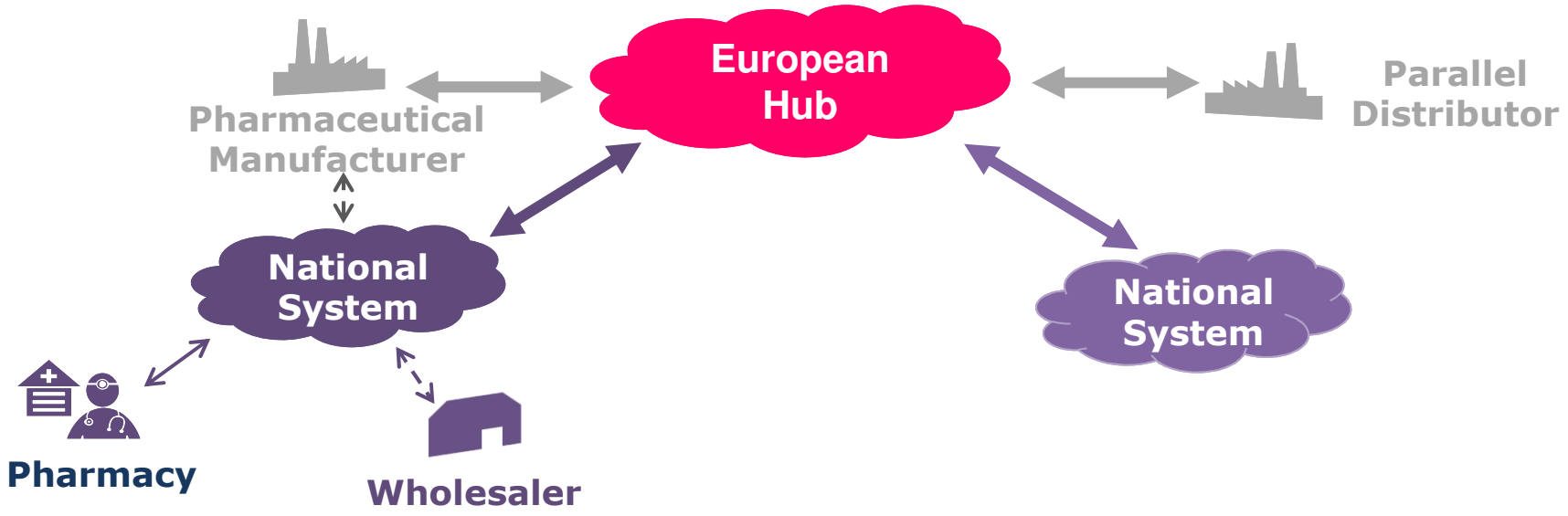


The **delegated Regulation (EU) 2016/161** "laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use":

- Was **published** in the Official Journal on 9th February 2016;
- It **applies as of 9th February 2019** in all MS;
- BE, EL and IT may defer the application by up to 6 years.

Repositories System Architecture

Distributed System



Source: ESM/EMVO

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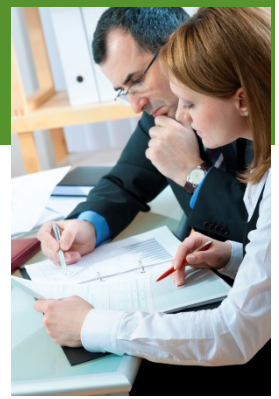
Supervision of the repository systems



Article 44 of Reg. 2016/161

- Supervision by national competent authorities (NCA) for any repository physically located in their territory, if necessary by means of inspections,
- Compliance with the requirements of the Regulation on safety features
- Possible delegation of obligations to another NCA or to a third party (written agreement)

Supervision of the repository systems

Article 44 of Reg. 2016/161

- A NCA can observe an inspection or conduct independent inspection of a repository in another Member States if such repository is used for the purpose of verifying the authenticity of medicinal products placed on the market in that Member State
- Communication of the reports of supervision activities to the European Medicines Agency
- Reports made available to the other national competent authorities and the Commission

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Supervision of the repository systems

Article 44 of Reg. 2016/161

- NCA may contribute to the management of any repository
- NCA may participate to the management board of the legal entities managing those repositories to the extent of up to one third of the members of the board

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EC Expert group on safety features

- **Aim**:
  - Facilitate the implementation of the safety features in the EU
  - Harmonise position on access to data, supervision, …
- 18th meeting held 12 October 2017
- One sub-group dealing with supervision (lead: Catherine Neary)
  - Participants: BE, DK, EE, FI, FR, DE, IE, LV, LT, PL, PT, SI, ES, SE, UK, EC, EMA, EDQM

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Mandate of the sub-group on supervision of the repositories system:

- Guideline for Member States supervision of the European Medicines Verification System
- Guideline for Member States supervision of national repositories
- Aide mémoire for inspection of repositories
- …
  - Report back to the expert group

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Latest update of the sub-group on supervision

- Key findings of EDQM conformity assessment of EMVS (location on on-boarding partners and use of gateway providers)

- Drafting of the inspection aide mémoire to be started following the next EDQM conformity assessment planned for Dec 17

- No obligation to conduct inspection prior Feb. 2019 but some NCA may wish to conduct pilot activity

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Topics for discussion

- Encouraging the signature of the IT contract (17 contract not signed, half of the EU is behind schedule)
- Reflect on the needs of hospitals, participation in the NMVO
- Discourage mandatory reimbursement number in the code for multimarket pack
- Scope of UI: most MS will not extend the scope (some exceptions for reimbursed OTC)
- Scope of ATD: most MS will not extend the scope, voluntary use often accepted

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Frequently asked questions (clarified in the Q&A)

- Costs of the system shall be borne by the manufacturer of medicinal products bearing the safety features
- Manufacturer can decide to the graphics on the containers and the Data Matrix added at the final packaging or in one set
- Wholesalers do not need (but can) to verify the integrity of the anti-tampering device
- Marketing authorisation holders are encouraged to exploit the residual storage capacity of the Data Matrix to include the information they would otherwise include in the QR

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New topics for discussion

- Use of labels: potential risks to be assessed ?
- Order of data elements in the 2D barcode
- Decommissioning by hospitals (use of aggregated code)
- …

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Conclusions

- Priority given to the setting up of the repositories system
- Supervision will be ensured by the NCA
- Safety features mandatory as of Feb. 2019
- All stakeholders on board
- EC and NCA ready to find pragmatic solutions

Thank you!

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Back-up slide- Extension of scope

Member State		Unique Identifier		Anti-Tampering Device			
		White List	Reimbursement	ATD on OTC	ATD removal from OTC	ATD on whitelist MP	Considering extending the scope of ATD?
Austria	AT	No	Not yet decided	Yes, voluntary	No	Yes, voluntary	-
Belgium	BE	Yes, if reimbursed	Yes	Yes, voluntary	No	Yes, voluntary	-
Bulgaria	BG	Under discussion	Under discussion	Under discussion	Under discussion	Under discussion	No information
Cyprus	CY	Under discussion	Under discussion	Under discussion	Under discussion	Under discussion	Yes
Czech Republic	CZ	No	No	Yes, voluntary	No	Yes, voluntary	-
Germany	DE	No	No	Yes, voluntary	No	Yes, voluntary	-
Denmark	DK	No	No	Yes, voluntary	Under discussion	Under discussion	Yes
Estonia	EE	No	No	Yes, voluntary	Under discussion	Under discussion	Yes
Greece	EL	Under discussion	Under discussion	Under discussion	Under discussion	Under discussion	Yes
Spain	ES	Yes, if reimbursed	Yes	Yes, voluntary	No	Yes, voluntary	-
Finland	FI	No	No	Yes, voluntary	No	Yes, voluntary	-
France	FR	Yes, if reimbursed	Yes	Yes	No	Yes	-
Croatia	HR	No	No	Yes, voluntary	No	Yes, voluntary	-
Hungary	HU	No	No	Yes, voluntary	Under discussion	Under discussion	No information
Ireland	IE	No	No	Yes, voluntary	No	Yes, voluntary	Yes
Italy	IT	No information	No information	No information	No information	No information	No information
Lithuania	LT	No	No	Yes under discussion	Under discussion	Under discussion	Yes
Luxembourg	LU	Under discussion	Under discussion	Yes, voluntary	Under discussion	Under discussion	Yes
Latvia	LV	No	No	Under discussion	Under discussion	Under discussion	Yes
Malta	MT	No	No	No	No	No	No
Netherlands	NL	No	No	Yes, voluntary	No	No	Yes
Poland	PL	No	No	Yes, voluntary	No	No	No
Portugal	PT	Yes, if reimbursed	Yes	Yes, voluntary	No	Yes, voluntary	-
Romania	RO	Under discussion	Under discussion	Under discussion	Under discussion	Under discussion	Yes
Sweden	SE	No	No	Under discussion	Under discussion	Under discussion	Yes
Slovenia	SI	Under discussion	Under discussion	Yes, voluntary	No	Yes, voluntary	-
Slovakia	SK	Under discussion	Under discussion	No	No	No	No
United Kingdom	UK	No	No	Yes, voluntary	No	Yes, voluntary	-
Norway	NO	No	No	Yes under discussion	Under discussion	Under discussion	Yes