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Health Products Regulatory Authority

Safety Features Update

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Health Products Distribution Inspector

HPRA GDP Information Day

3rd May 2022

Radisson Blu Royal Hotel, Dublin

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Overview

- Delegated Regulation (EU) 2016/161
- Wholesaler requirements
- 'Use and learn' Phase
- Plan to exit 'Use and learn' phase
- Areas for consideration for wholesalers post 'Use and learn'

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Delegated Regulation (EU) 2016/161

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- Delegated Regulation (EU) 2016/161 supplements the Falsified Medicines Directive 2011/62/EU.
- Sets out detailed rules for the safety features appearing on the packaging of medicinal products for human use
- Obligations of manufacturers, marketing authorisation holders (MAH), wholesalers and individuals entitled to supply the public.

- 9th February 2019

Delegated Regulation (EU) 2016/161

Anti-tampering device

Safety features

Unique Identifier

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Wholesaler requirements

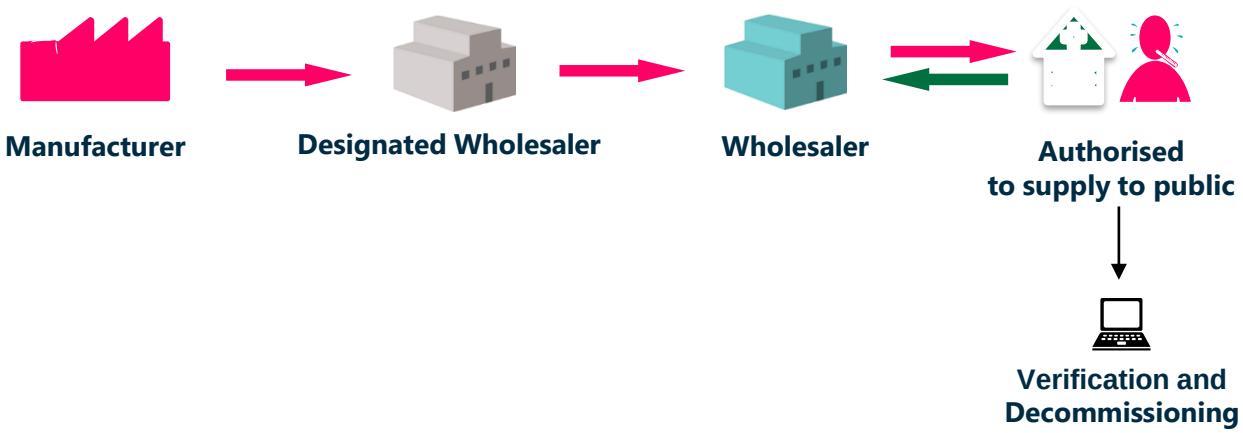
Wholesaler requirements - Verification

- Medicinal products returned by persons authorised or entitled to supply medicinal products to the public or by another wholesaler .

- Medicinal products received from a wholesaler who is not the **manufacturer**, the **marketing authorisation holder** nor the **designated wholesaler** (wholesaler who is designated by the marketing authorisation holder, by means of a written contract, to store and distribute the products covered by his marketing authorisation on his behalf)

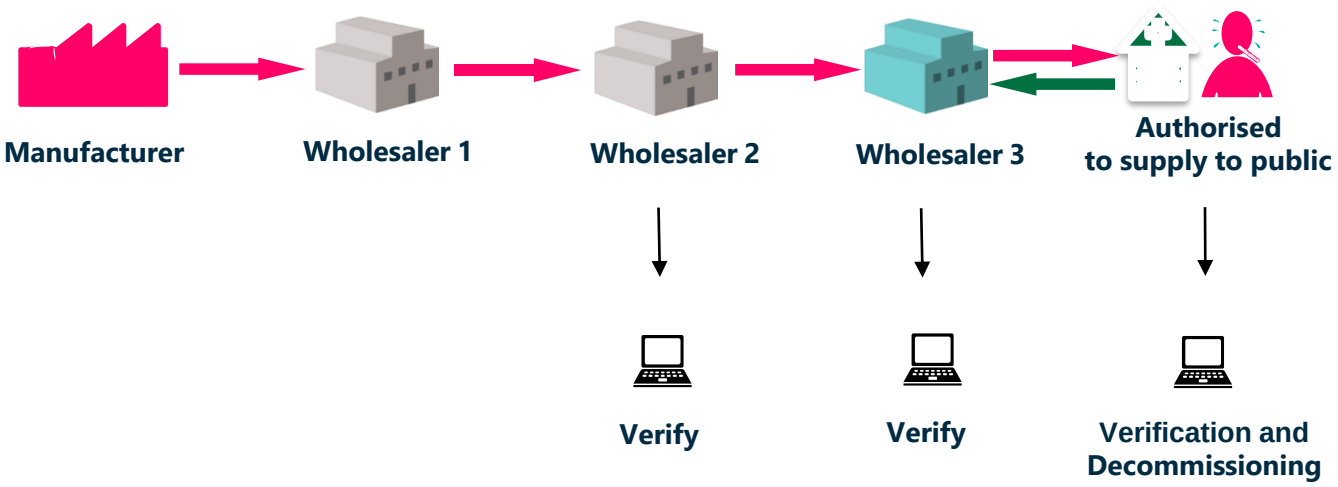
Wholesaler requirements - Verification

Example 1:



Wholesaler requirements - Verification

Example 2:



Wholesaler requirements - Verification

- Scan the 2D barcode so that the unique identifier is verified against the repository system
- Check details on the repository system match the details of the physical product
- Physical check on the integrity of the anti-tampering device
- **Verification can be done any time after receipt but must be done prior to dispatch**

Wholesaler requirements - Verification

Exceptions

- The medicinal product changes ownership but remains within the physical possession of the same wholesaler

- Medicinal product is distributed within the territory of the Member State between two warehouses belonging to the same wholesaler or the same legal entity and no sale takes place

Article 21

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Wholesaler requirements - Decommissioning

- It is the operation of changing the active status of a unique identifier stored in the repositories system to a status impeding any further successful verification of the authenticity of that unique identifier

Wholesaler requirements - Decommissining

When

- Export
- Returns (that can not be returned to saleable stock)
- Destruction
- Samples for competent authority
- Products distributed to persons authorised or entitled to supply medicinal products to the public who do not operate within a healthcare institution or within a pharmacy: veterinarians , dental practitioners; optometrists and opticians; paramedics and emergency medical practitioners.

Article 22 & 23

Wholesaler requirements - Decommissioning

Reversing the status

- The reverting operation is conducted by the same entity (under the same authorisation) as the person that decommissioned the unique identifier
- It takes place not more than 10 days after it was decommissioned
- The medicinal product is not expired, recalled, withdrawn, intended for destruction or stolen
- The medicinal product has not been supplied to the public

Article 13

Wholesaler requirements – Suspected falsified medicinal products

- Wholesalers shall not supply or export a medicinal product where it has reason to believe;
  - Packaging tampered with or,
  - Verification of unique identifier indicates that it may not be authentic

Notify the HPRA immediately

Article 24

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‘Use and Learn’ Phase & plan to exit

‘Use and learn’ phase:

- Ireland has been in a ‘use and learn’ phase since 9th February 2019

- Permitted wholesalers, hospitals and pharmacies to supply medicines that had generated alerts on scanning, provided there were **no overriding concerns regarding falsification.**

Ending ‘use and learn’ phase:

- The National Safety Features Oversight Group;
  - Irish Medicines Verification System (IMVO)
  - Health Products Regulatory Authority (HPRA)
  - Department of Health (DoH)
  - Health Service Executive (HSE)
  - Private Hospitals Association (PHA)
  - Pharmaceutical Society of Ireland (PSI)

- Phased approach, consisting of seven phases, to ending the ‘use and learn’ phase starting in Q3 2021 and ending during Q2 2022.

Ending ‘use and learn’ phase:

Timing	Phase	Details	Notes
Q3 2021	**Phase 1** *Pilot programme with wholesalers.*	Primary wholesalers to scan sample of packs at goods inwards and quarantine them if there are alerts until the issues were resolved by MAHs or WDA	**Completed** **5.3% alert rate** **97% alerts due to data not on IMVS** **All alerts resolved in 2 days. No impact to supply**

Ending ‘use and learn’ phase:

Timing	Phase	Details	Notes
10th September 2021	**Phase 2** *Red, Amber, Green (RAG) changes for wholesalers*	WDA FMD software to display RAG colour coded responses (depending on outcome when pack is scanned) (prior to that, all systems showed green even if alert generated)	**Completed**

Ending ‘use and learn’ phase:

Timing	Phase	Details	Notes
28th February 2022	**Phase 3** *Use & learn ends for returns to wholesalers*	All alerts generated when scanning returned packs must be investigated, and suspected falsification ruled out.	**Completed**
	Phase 4 *RAG changes for pharmacies & hospitals*	Pharmacy and hospital FMD software to display RAG colour coded responses, depending on outcome when pack is scanned	

Ending ‘use and learn’ phase:

Timing	Phase	Details	Notes
Start of April 2022* ***Rolling basis to end of May 2022**	**Phase 5** *Pilot of alert handling procedures with pharmacies, hospitals and wholesalers*	Pilot of alert handling process. All alerts generated as a result of scanning activity should be investigated but it is not necessary to withhold packs from supply until the alert is resolved.	**Commenced**

Ending ‘use and learn’ phase:

Timing	Phase	Details	Notes
9th May 2022	**Phase 6** *Use & learn ends for wholesalers for all remaining activities*	All alerts generated by wholesalers must be investigated, and suspected falsification ruled out, before the relevant packs may be returned to saleable stock or supplied	**n/a**

Ending ‘use and learn’ phase:

Timing	Phase	Details	Notes
30th May 2022	**Phase 7** *End of use & learn for pharmacies and hospitals*	All alerts generated by pharmacies and hospitals must be investigated, and suspected falsification ruled out, before the relevant packs may be supplied	**n/a**

Communication with Stakeholders

- The Safety Features Oversight Group has engaged with impacted stakeholders on a frequent basis with each competent authority responsible for communicating with the stakeholders they regulate.

  - Targeted written communications to wholesalers, hospitals & pharmacies
  - Pilot programmes to identify specific issues
  - Interactive information sessions from IMVO for wholesalers, pharmacies and hospitals
  - IMVO currently developing alert handling guidance
  - IMVO will have a helpline for pharmacies/hospitals once 'use and learn' over

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Areas for consideration post ‘Use and Learn’ Phase

End of ‘Use and Learn’ for Wholesalers – some considerations

- **Ensure procedures and practices are future proof.**
- Don’t forget about the tamper evident seal!
- Maintain records of any decommissioning or verification activities conducted.

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End of ‘Use and Learn’ for Wholesalers – some considerations continued

- **Consider a policy on returns**
- Continue to engage with HPRA and IMVO.
- Reference IMVO Alert Handling Guidance

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Resources

- Falsified Medicines Directive 2011/62/EU
- Commission Delegated Regulation (EU) 2016/161
- Irish Medicine Verification Organisation website
- European Commission website

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Thank you