WG IV: Implementation of the Falsified Medicines Directive in the hospital setting[1]

Adopted 25 September 2018 by the Member State expert group on the safety features[2]

Executive summary

The deadline for the entry into application of the safety features is fast approaching. Hospitals must be ready to decommission safety features by 9 February 2019. Hospitals should start preparations early to ensure they have the necessary equipment and personnel to comply with the requirements of the Falsified Medicines Directive and Commission Delegated Regulation by this date.

Decommissioning in hospitals can be accomplished by scanning individual unique identifiers or, if agreed with suppliers, by scanning aggregated codes. Although aggregation through the repository system will not be ready by 9 February 2019, some manufacturers and wholesalers may be able to provide grouped unique identifiers to hospitals.

Context

In order to secure the legal supply chain of medicinal products, the Falsified Medicines Directive 2011/62/EU (FMD) and Commission Delegated Regulation (EU) 2016/161 (DR) have introduced a new end-to-end verification system for medicinal products subject to prescription. The end-to-end verification is a medicines authentication system including mandatory safety features and a repository that stores information on each individual pack.

The new rules will become applicable in the EU and EEA on 9 February 2019. From this date, prescription medicines sold in the EU will need to carry a unique identifier (UI) and anti-tampering device (ATD).

Decommissioning by hospitals

From 9 February 2019, hospitals will need to verify the safety features on prescription medicines (UI and ATD) and decommission the UI before supply to the patient. Considering that hospitals receive large volumes of medicinal products which are administered to the patient at ward level, decommissioning may take place at any time the medicine is in the physical possession of the healthcare institution, as long as no sale takes place between delivery and supply.

Hospitals must ensure that they have the necessary equipment and personnel to decommission UIs. This includes purchasing scanners to read the unique identifiers, ensuring enough personnel to fulfil the verification duties and upgrading software to connect to the repository system. Automated stock management systems may facilitate this task by allowing for automatic inbound scanning, storage, fetching and outbound scanning, including potential decommissioning of medicinal products.

[1] This paper is relevant for persons entitled to supply medicines to the public in a hospital setting, such as hospital pharmacies.

[2] http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=2719

Another solution to facilitate decommissioning by hospitals is the use of aggregation that allows decommissioning multiple UIs from a specific shipment. This shipment would be identified by an additional barcode[3]. Although the DR does not require aggregation, manufacturers, wholesalers or parallel traders may provide or use aggregated codes on a voluntary basis.

Ideally, for security reasons, this aggregation should be fully integrated into the EU repository system (EMVS and NMVSs). Unfortunately, aggregation through the EMVS and NMVSs will not be available by 9 February 2019. Hospitals associations on the boards of the EMVO and NMVOs should work with the pharmaceutical industry and wholesalers to discuss the possibility of standardised systems for aggregation via the repository system in the longer term. Stakeholders estimate 3 to 5 years to develop full aggregation.

A temporary solution, until aggregation via the EMVO and NMVOs is available, is decommissioning through data files. Under this solution, shipments are identified by standardised files containing a list of UIs (containing product code, random number, expiry date, batch number), as well as other potentially relevant data (handling instructions, etc)[4]. These data files should be matched to physical shipments by an additional barcode[5]. Once a shipment has been matched to a data file, hospitals can then use the list of grouped UIs to decommission all products in the shipment without the need to scan each individual UI.

In order to receive shipments including data files with grouped UIs, including the scenario as described in Q&A on safety features question 6.6[6], hospitals must contact their direct suppliers to ask if they are able to provide grouped UIs. This service may entail additional costs. Hospitals should be aware that complex supply chains are more often implicated in incidents of falsification. Hospitals should preferably request aggregated codes or data files from marketing authorisation holders, manufacturers or designated wholesalers, as the hospitals bear the ultimate responsibility for verifying safety features before supply to patients.

Furthermore, the creation of data files should be based on a contract between the hospital and supplier. The exchange of the data file should be encrypted, secure , confidential and documented in the contract with the supplier. Furthermore, the files should be sent separately by secure means. Hospitals are reminded to always check the legitimacy of suppliers, for example through EudraGMDP[7].

Additional security checks for aggregated or grouped codes

Persons supplying medicines to patients in hospitals bear the ultimate responsibility of verifying and decommissioning UIs on prescription medicines. Since they will not verify each individual UI in a shipment, those receiving and decommissioning aggregated or grouped codes should perform additional checks to ensure the aggregated codes or data files are authentic and match the products received. In particular, they should at least verify, where applicable using their pharmacy software, that:

- the usual checks on reception confirm the number of packages received corresponds to the number of unique identifiers included in the aggregated barcode or data file;
- the shipment has been packaged in a way that makes it difficult to extract individual packages (e.g. shrink wrapping, sealed tertiary packaging, tamper-evident closure); and,

[3] Such as the GS1 Serial Shipping Container Code.
[4] Examples of standardised data file formats are GS1 EANCOM and GS1 XML.
[5] Such as the GS1 Serial Shipping Container Code.
[6] https://ec.europa.eu/health/sites/health/files/files/falsified_medicines/qa_safetyfeature_en.pdf
[7] http://eudragmdp.ema.europa.eu/

- the scanning of a statistically relevant random sample of packages is found to correspond with the information in the aggregated code/data file.

Only when all the conditions outlined above are met can decommissioning through the aggregated code or data file take place. If these conditions are not met or verification/decommissioning fails, the shipment must be handled as suspect and applicable national guidance should be followed. Subject to further checks, medicines may be dispensed after ensuring they have been individually verified and decommissioned. Checking ATDs is also required before supply to the patient.

Conclusions

Persons supplying medicines to patients in hospitals must be prepared to verify safety features and decommission UIs from 9 February 2019. The simplest and most desirable solution for security reasons is to manually decommission each individual package. Automated scanning may help to facilitate this task.

Some hospitals, depending on their suppliers, may also be able to obtain grouped UIs that allow them to decommission multiple UIs at once. This should only be considered a temporary solution until full aggregation through the repository system is available. Additional verifications should also be undertaken to mitigate some of the risks associated with decommissioning grouped UIs. Hospitals pharmacists should be aware that they have the final responsibility for ensuring medicines administered to patients are authentic and decommissioned before supply.

Next steps

Stakeholders (manufacturers, wholesalers) have expressed willingness to discuss the development of standardised systems for aggregation through the repository systems. The expert working group encourages all stakeholders to start these discussions to ensure a long term solution for hospitals receiving large shipments is found. Feedback on the discussions to the European Commission, the expert working group and the respective national competent authorities is welcomed.