

Impact of the implementation of the Falsified Medicines Directive on a healthcare institution

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Background

The Directive 2011/62/EU (Falsified medicines directive, FMD) provides for measures to prevent the entry into the legal supply chain of falsified medicinal products and has been supplemented by the commission delegated regulation (EU) 2016/161. From February 2019 on prescription medicines are required to bear individual safety features that need to be verified and decommissioned by pharmacies before supplied to the public. While this process has already been tested in some community pharmacies, little is known on the implications the FMD has on healthcare institutions.

Aim of the present study was to assess the impact of the implementation of the legal requirements under the FMD in a University based hospital pharmacy.

Methods

In order to simulate the 'end-to-end' verification as outlined by the directive, packs of prescription medicines were randomly scanned at goods in and at several points of dispense within the pharmacy. The time required to process the respective number of drugs was measured and clustered for the individual product type.

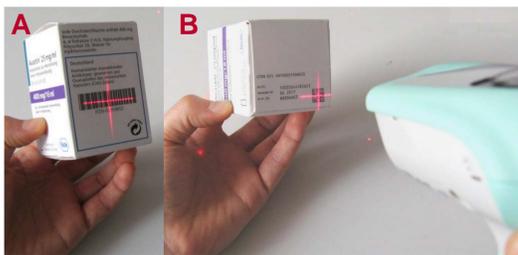


Fig. 1: Scanning of A) 1D Barcode B) 2D Matrixcode



Fig. 2: Boxes and pallets at goods-in



Fig. 3: Representative points of dispense (goods-out)

Results

A total of 1,546 packs of 59 different medicinal products were assessed at goods in, which took a median of 2.1s (0.6-6.5s) to process each single pack. However, some drugs such as iv-anaesthetics, iv-antibiotics and iv-painkillers, all of which were stored on pallets, required a significantly higher amount of time to verify. The simulation was repeated at four different points of dispense where 2,056 packs of 811 different drugs were scanned. Here the amount of time required was not significantly different from goods in.

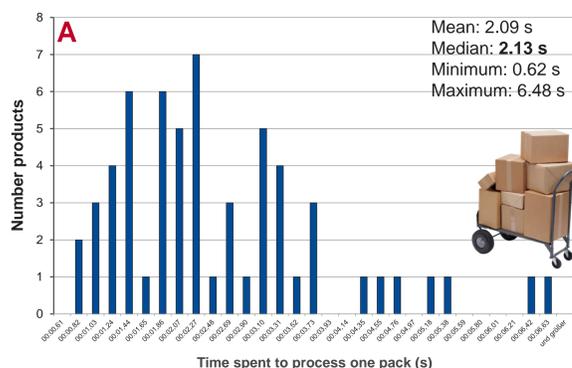
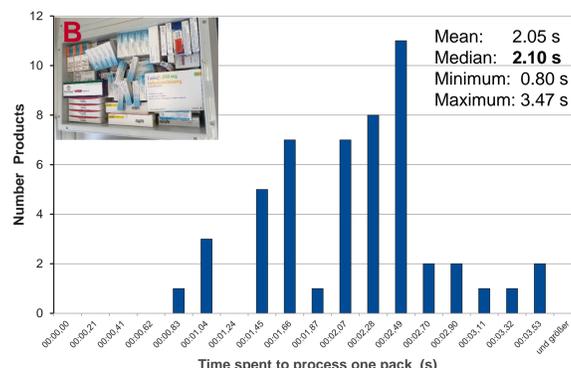
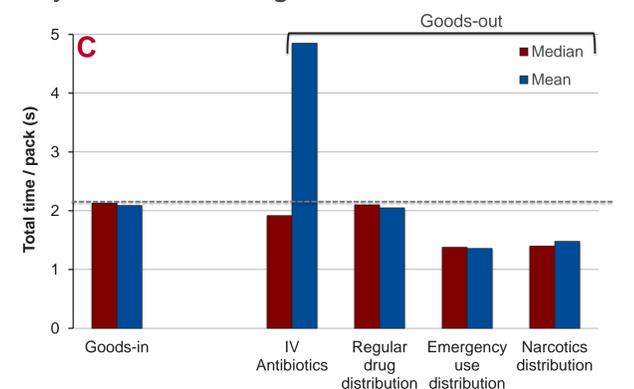


Fig. 4: Time needed to process a single pack: A) Goods-in,



B) Goods-out



C) Comparison of different sites in the pharmacy, where verification and decommissioning could take place

Based on these data we calculated the total amount of time needed to process all prescription drugs in our pharmacy that potentially fall under the delegated regulation: **2.6 Mio. Packs x 2.1 s = 5.46 Mio. s \approx 1,500 h.**

This corresponds to a demand of 1-2 full time equivalents of persons authorised or entitled to supply medicinal products to the public.

The verification and decommissioning of the unique identifier could be aided by incorporation of the process in robotic dispensing systems or by using logistic tools such aggregated codes. Due to the fact that neither the European (EMVO) nor the National Medicines Verification Organisations (NMVO) are as yet able to process such codes, we have made suggestions that the manufacturers offer to electronically transmit a file holding the respective serial numbers of the respective shipment upon delivery to the pharmacy. A schematic model of such a process is shown in figure 5. A proof of concept is currently on the way in our pharmacy. However, such proposals rely on the willingness of the manufacturers to implement the respective procedures in their workflow. Discussions with pharmaceutical companies, the German NMVO and the EMVO in order to create best practice recommendations with respect to the FMD in the hospital are on the way.

Conclusion

Our study demonstrates that the implementation of the FMD in the hospital pharmacy is a major challenge. Compared with the community pharmacy, a much greater degree of planning, organization and technical support is needed to cope with the decommissioning of large numbers of drugs. In addition, several questions such as whether and how drugs that are shipped from a hospital pharmacy to another healthcare institution that belongs to a different provider are dealt with, need to be answered by the national competent authorities.

References

Falsified Medicines Directive: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2011_62/dir_2011_62_en.pdf

Commission Delegated Regulation (EU) 2016/161: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2016_161/reg_2016_161_en.pdf

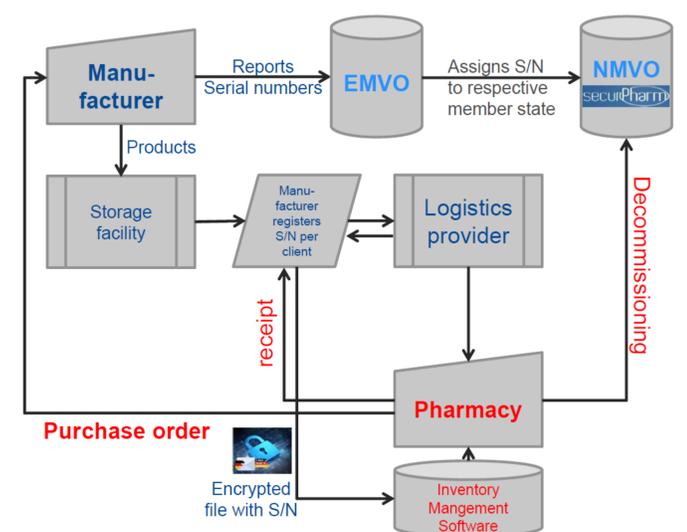


Fig. 5: Suggested process in which manufacturer transmits S/N of the respective shipment electronically