FIVE YEARS OF THE FALSIFIED MEDICINES DIRECTIVE: A COMPARATIVE ANALYSIS OF COMPLIANCE AND IMPACT IN HOSPITAL PHARMACY

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BACKGROUND AND IMPORTANCE

The Falsified Medicines Directive (2011/62/EU) (FMD), effective from February 9, 2019, establishes rules to prevent falsified medicines from entering the legal supply chain, ensuring authenticity and traceability to enhance patient safety.

While FMD provides valuable monitoring data, incomplete implementation impairs its full effectiveness.

AIM AND OBJECTIVES

To verify compliance with the FMD five years after its implementation and to compare the impacts in hospital pharmacy six months after the initial implementation.

MATERIALS AND METHODS

Elaboration of a form (MS-Excell®) with the purpose of systematizing data

Products received between August 21 and 30, 2024, were analyzed and compared with products received from September 18 to 27, 2019

Products not requiring a Unique Identifier Code (UIC) were excluded

The following parameters were analyzed:

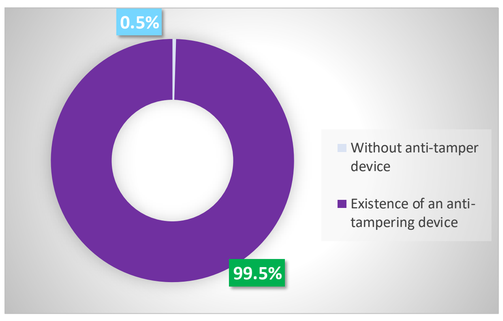
- Presence of the unique identifier code (UIC);
- Existence of an anti-tampering device (ATD);
- Start time and end time of code scan;
- Appearance issues with scanning procedure.

RESULTS

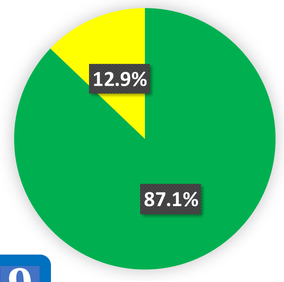
Comparative analysis of 163 products in 2024 (10611 packages) versus 201 products in 2019 (10935 packages), that requiring a Unique Identifier Code (UIC)

2019 **69%** → Unique Identifier Code Present → **100%** 2024

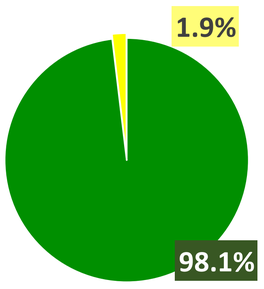
In 2024, 99.5% of products had an ATD



SCANNING PROCEDURE



2019



2024

Reading issues decreased to 1.9% in 2024 compared to 12.9% in 2019

	Total Number of Orders	Orders with UIC Present	Total Packages	Average Time for Analysis 1 code (seconds)	Average Time Hours (8 working days)
2024	163	163	10611	8,57	25,3
2019	201	140	10935	9,52	29

The average time for scanning a unique identifier code includes:

- Connecting software,
- Verifying the safety device,
- Positioning packaging for scan read,
- Wait for the scan read confirmation.

THE AVERAGE UIC READING TIME REDUCED FROM 9.5 SECONDS IN 2019 TO 8.57 SECONDS IN 2024

29 versus 25 working hours in 8 working days

CONCLUSION AND RELEVANCE

- ✓ The verification of medications focuses on patient safety, ensuring the authenticity and integrity of the product. This practice is an essential tool to guarantee the quality and safety of medicines in the pharmaceutical profession. The analysis reveals a substantial improvement in compliance with the FMD, as evidenced by the increase in UIC implementation and the high rate of ATD presence, reflecting progress in enhancing patient safety.
- ✓ The results of this study allow us to conclude that, five years after the directive came into effect, laboratories are generally complying with its requirements, as all the analyzed products have a Unique Identifier, and only 0.5% do not have a DPA.
- ✓ This includes outpatient products, where scanning at the point of dispensing could provide additional benefits, such as improved pharmacovigilance and pharmacoepidemiology.
- ✓ The reduction in scanning issues and faster reading times are likely due to technological advancements and improved operational processes. However, challenges remain, including the time required to verify safety features, which totals 25 hours over 8 working days (0.45 ETC) in 2024, and ensuring the directive's full benefits for patient care, particularly in countries with limited implementation and low connection of hospital pharmacies. Addressing these issues will be crucial in realizing the FMD's full potential for improving patient care.

References:
Directive 2011/61/EU

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