IMPACT OF THE IMPLEMENTATION OF THE FALSIFIED MEDICINES DIRECTIVE AT THE LISBON PORTUGUESE INSTITUTE OF ONCOLOGY (FG, EPE)

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WHAT WAS DONE

To prevent the introduction of falsified medical products into supply chains, on 9 February 2019, the directive 2011/62/EU started to be applied.

This legislation has allowed the implementation of measures to ensure the authenticity and high levels of traceability, providing greater patient safety.

WHY WAS DONE

Assess the impact in the implementation of the falsified medicines directive after 6 months on the entry into force of the new legislation.

HOW IT WAS DONE

Elaboration of a form (MS-Excell®) with the purpose of systematizing data. Of all products prescribed between 18 and 27 September 2019, products not covered by the requirement of unique identifier code were excluded.

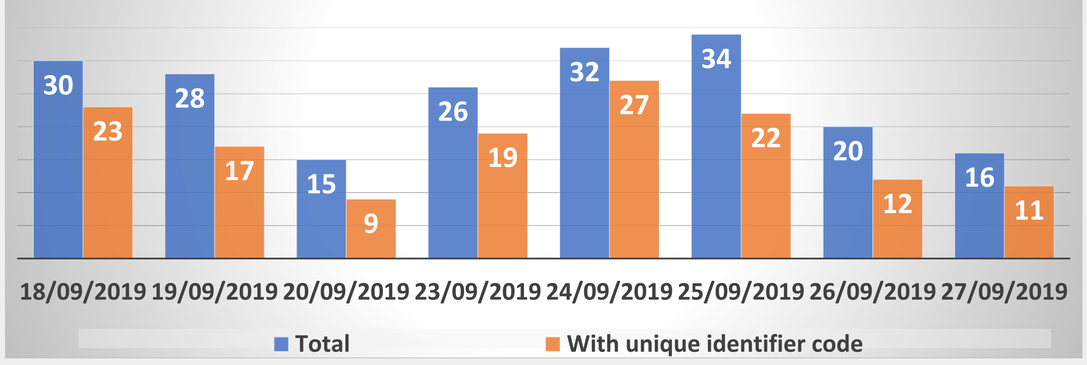
The following parameters were analyzed:

- Presence of the unique identifier code;
- Start time and end of code scan;
- Appearance of problems with scanning procedure.

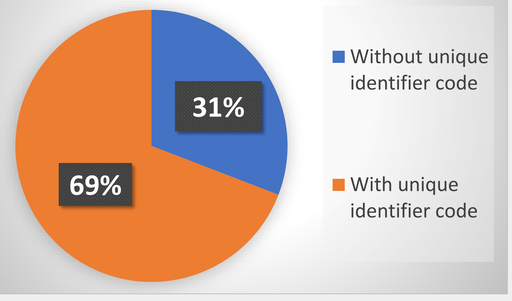
WHAT WAS ACHIEVED

- 201 products were analyzed. About 69% of the products have unique identifier code.
- Of the products intended to be dispensed for outpatients, only 70% had unique identifier.
- After reading 10935 packages, it was found that, on average, the reading of 12.9% of the products with unique identifier code had at least one scanning issue.
- The average time for reading a unique identifier code was 9.5 seconds, that includes:
  - ✓ Connecting software,
  - ✓ Verifying the safety device,
  - ✓ Positioning packaging for scan read,
  - ✓ Wait for the scan read confirmation.

Total of Orders vs Orders with Unique Identifier Code

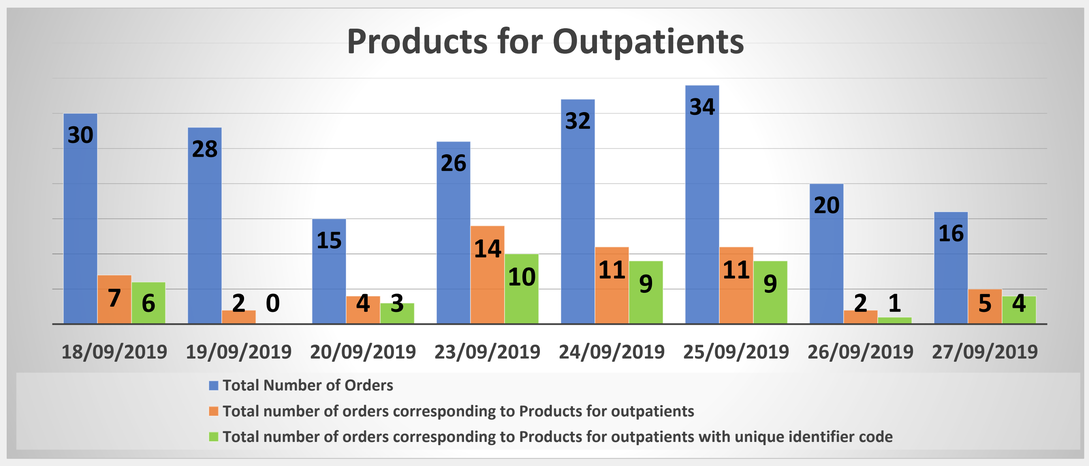


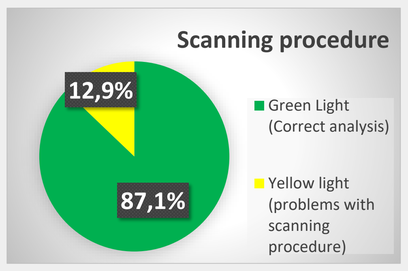
Representation in a Total of 201 Orders



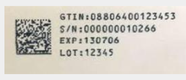
AFTER 6 MONTHS THE IMPLEMENTATION OF THE FALSIFIED MEDICINES DIRECTIVE ONLY ABOUT 69% OF THE PRODUCTS HAVE UNIQUE IDENTIFIER CODE.

Products for Outpatients





Example of unique identifier code:



	Total Number of Orders	Orders with Unique Identifier Code Present	Total Number of Unique Identifier Codes Analyzed	Average Time for Analysis 1 code (seconds)
TOTAL	201	140	10935	9,52

9,5'' REPRESENTS A ROUND 29 WORKING HOURS IN 8 WORKING DAYS

WHAT IS NEXT

After 6 months of the entry into force of the counterfeit medicines Directive, about 31% of the products received in the hospital pharmacy do not yet have unique identifier code. And this includes products for outpatients, were scanning at dispensing could be a relevant added value.

Reading time of the unique identifier code represents around 29 working hours in 8 working days, or 0,5 ETC (7 hours working day).

The implementation of this directive implied investments in software, material and human resources, the internal work procedures were reorganized as well.

Direct advantages for patient care are not yet evident as the unique identifier is still not fully implemented.

GIP:2SPD-017 25th Congress of the EAHP Gothenburg, March 2020