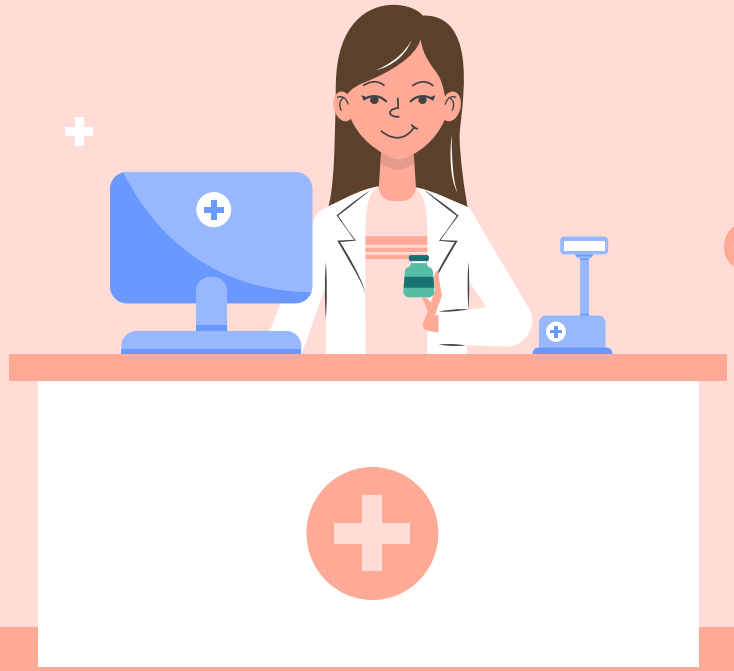
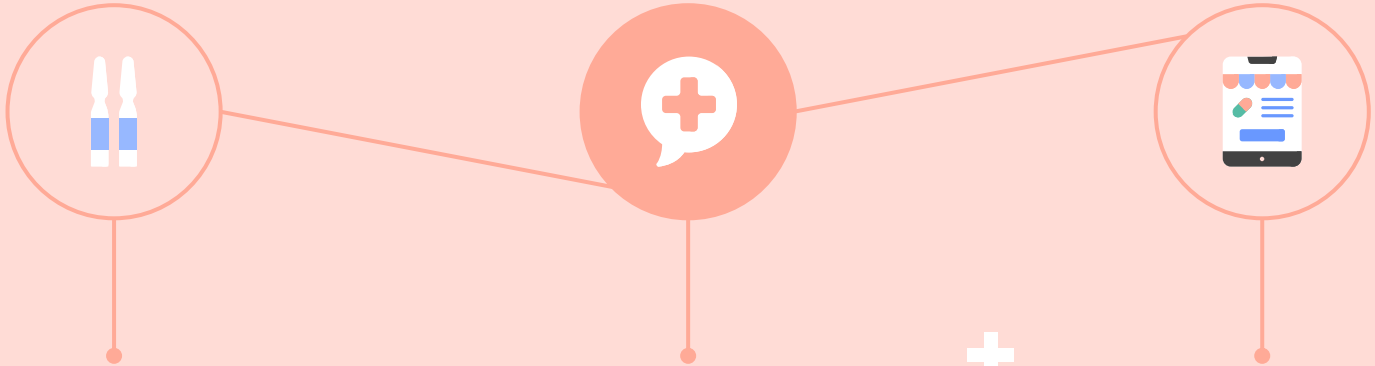


WHAT DOES TRACK &TRACE MEAN FOR THE COMMUNITY PHARMACIST?

Jaime Acosta-Gomez
SPAIN

Supply chain security of medical products

PHARMACY IN SPAIN



MEDICINES

Pharmacy only.
Rx-non Rx.

PHARMACIES

Privately owned.
Pharmacists only.
No branches.

ePHARMACIES

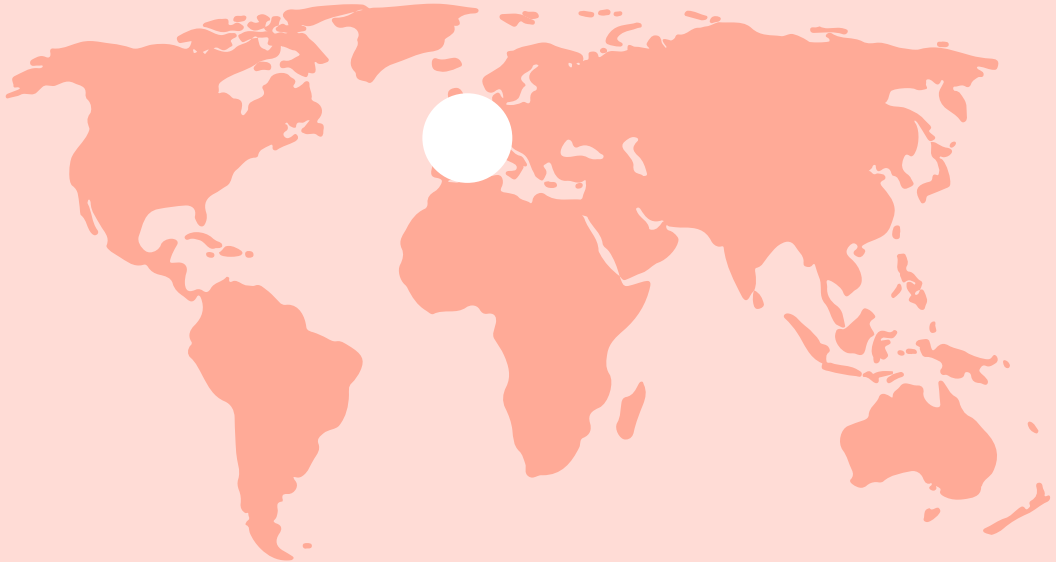
Only brick and mortar.
Non Rx only

FAKE MEDICINES IN THE LEGAL CHANNEL

0%

Strict regulation in the legal medicines supply chain: wholesalers and pharmacies.

Legal framework – The Falsified Medicines Directive. EU



Following adoption by the European Council and the European Parliament, the Falsified Medicines Directive (Directive 2011/62/EU) was published on 1 July 2011, and applies since 2 January 2013

DIRECTIVE 2011/62/EU MEASURES INCLUDE

01

SAFETY FEATURES

A unique identifier and an anti-tampering device

02

COMMON EU WIDE LOGO

To identify legal online pharmacies

03

IMPORT OF ACTIVE PHARMACEUTICAL INGREDIENTS

Tougher rules

04

WHOLESALE DISTRIBUTORS

Strengthened record-keeping requirements

01

SAFETY FEATURES

Into application since 9 February 2019

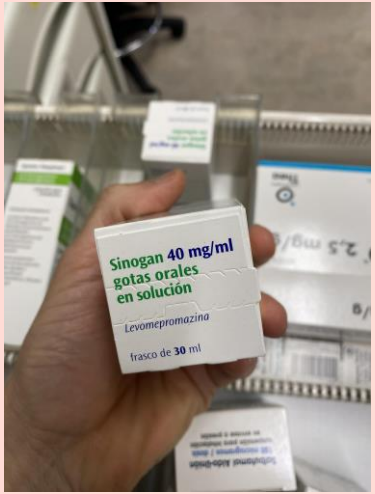
UNIQUE IDENTIFIER (IU)

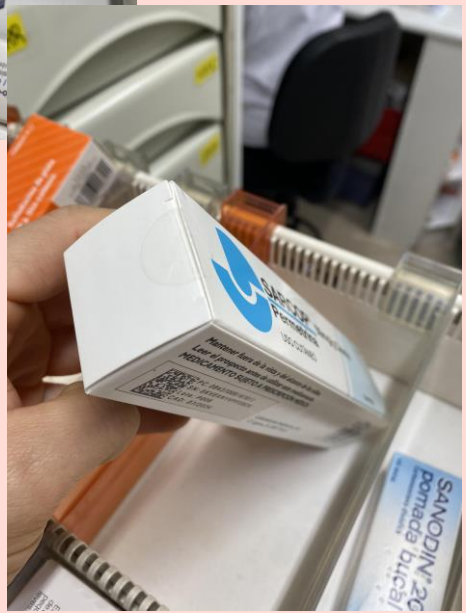
Alphanumerical code enabling the identification and authentication of individual packs.
Uploaded to a central EU repository

ANTI TAMPERING DEVICE

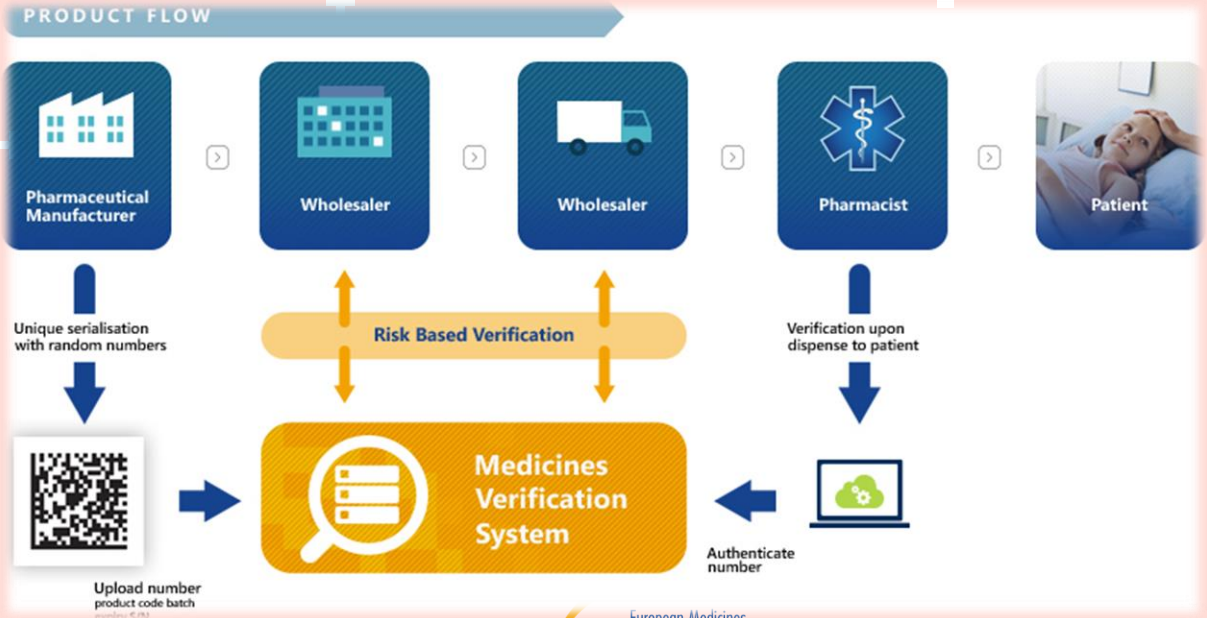
Device allowing the verification of whether a pack has been opened/tampered with.

ANTI TAMPERING DEVICE

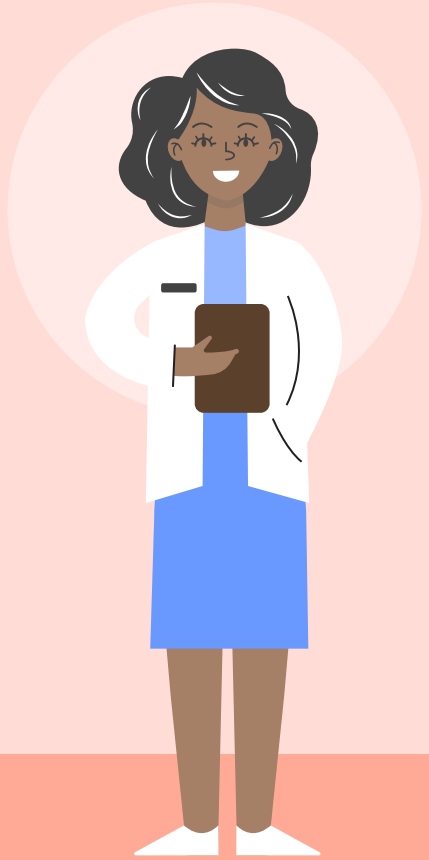




PRODUCT FLOW



emvo European Medicines Verification Organisation



A functioning, secure, interoperable and cost effective system across Europe.

PC:	09876543210982
SN:	12345AZRQF1234567890
NN:	(optional)
Batch:	A1C2E3G4I5
Expiry:	180531

Illustrative example – not binding

The UI will contain:

- Product code: ISO-compliant (ISO 15459); < 50 characters; globally unique; issued by ISO-compliant coding agencies;
- Serial number (max 20 characters; randomised)
- A national reimbursement or identification number (optional)
- Batch number
- Expiry date

VERIFICATION SYSTEM

PC:	09876543210982
SN:	12345AZRQF1234567890
NN:	(optional)
Batch:	A1C2E3G4I5
Expiry:	180531

Illustrative example – not binding

A

END TO END

Manufacturers/authorisation holders.
Pharmacies and hospitals.

B

MIDDLE OF THE CHAIN?

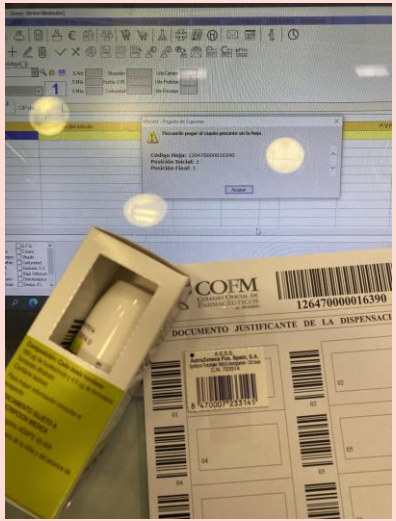
Risk-based verification

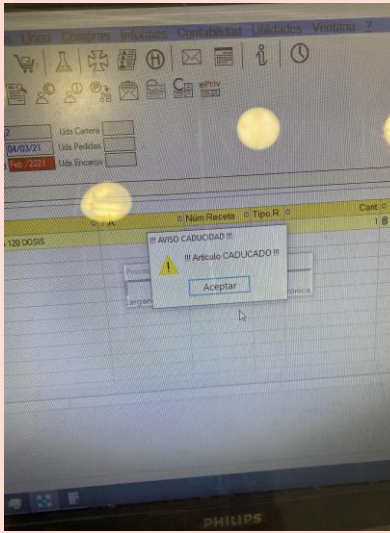
C

REVERSING A DECOMMISSIONED UI

Returning to an active status, under certain conditions

HOW DOES IT WORK IN PRACTICE?



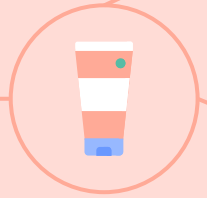


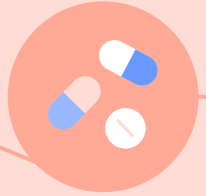
OTHER CONSIDERATIONS

01
Automatic decommission of expired medicines/recalled batches

02
Non dispensing to final patients (dental clinics, prisons, nursing homes)

03
Damaged/medicines taken for inspection decommissioned too





04
Manufacturers as distributors

SURVEY

Survey with 16 questions to Spanish pharmacists.

In Spanish.

Spread through social media (Twitter, Facebook, Whatsapp, Telegram, email...).

Open 5 days (20 Feb-26 Feb 2021).

RESULTS RELATED TO RESPONDENTS

01

456 RESPONDENTS

Number of valid answers

02

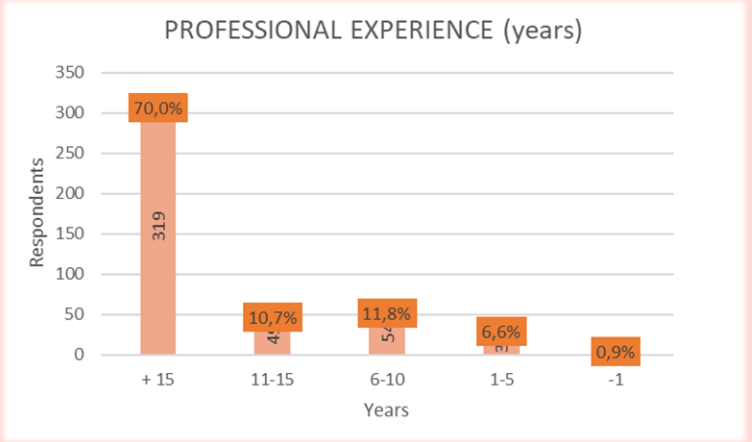
448 (98,2%) COMMUNITY PHARMACY

Practice setting

03

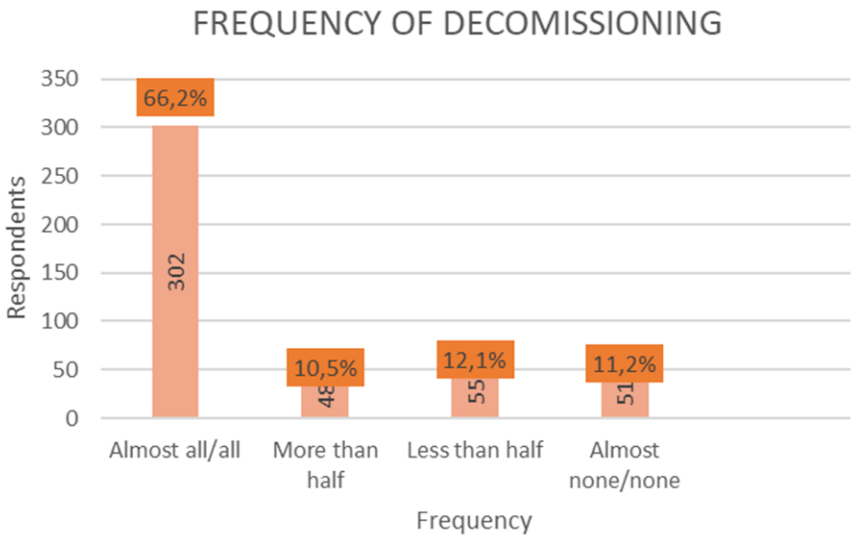
EXPERIENCED RESPONDENTS

91% +6 years



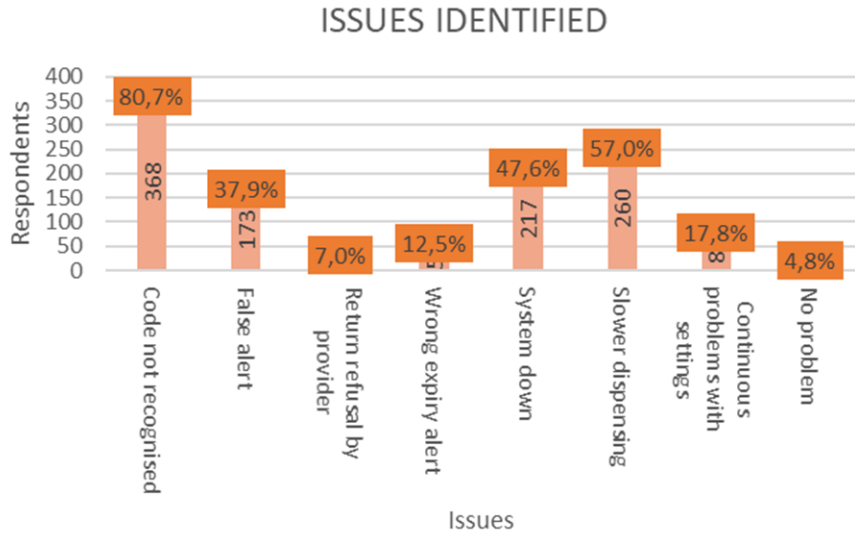
USAGE

66,2% of respondents use the system with every package



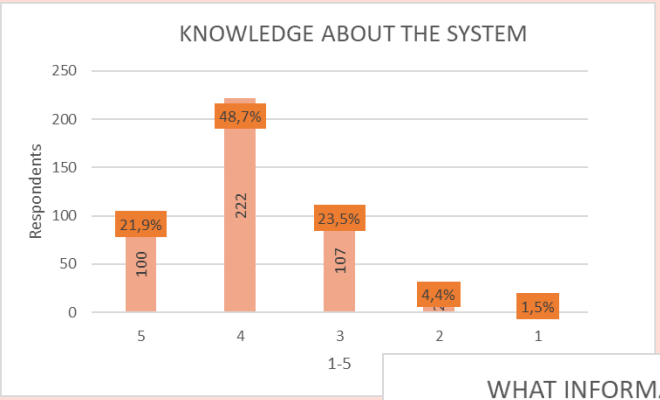
ISSUES

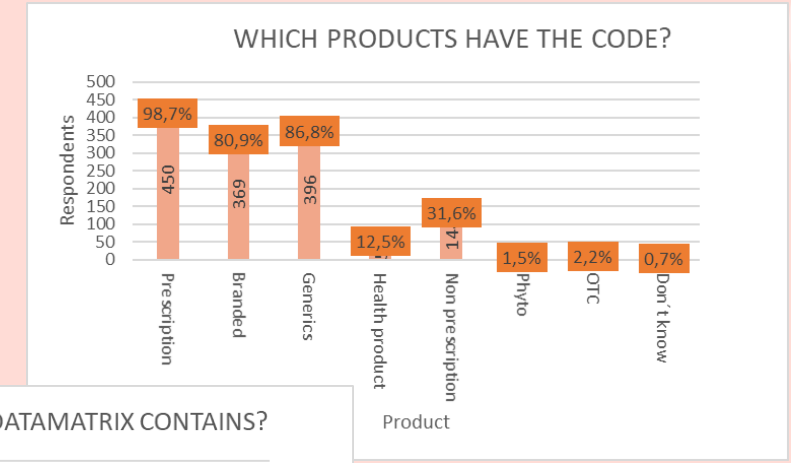
Young and complex system; still needs more time

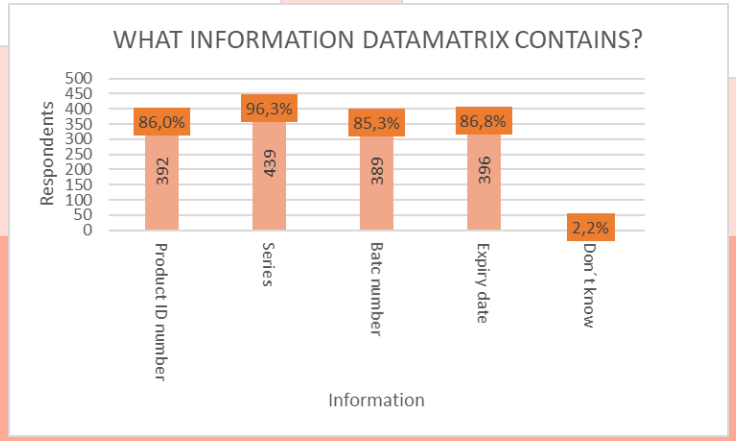


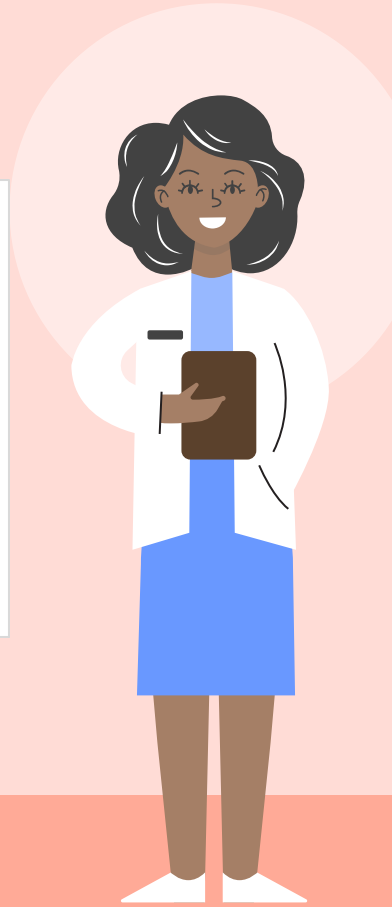
KNOWLEDGE

Repondents have right information; still room for improvement

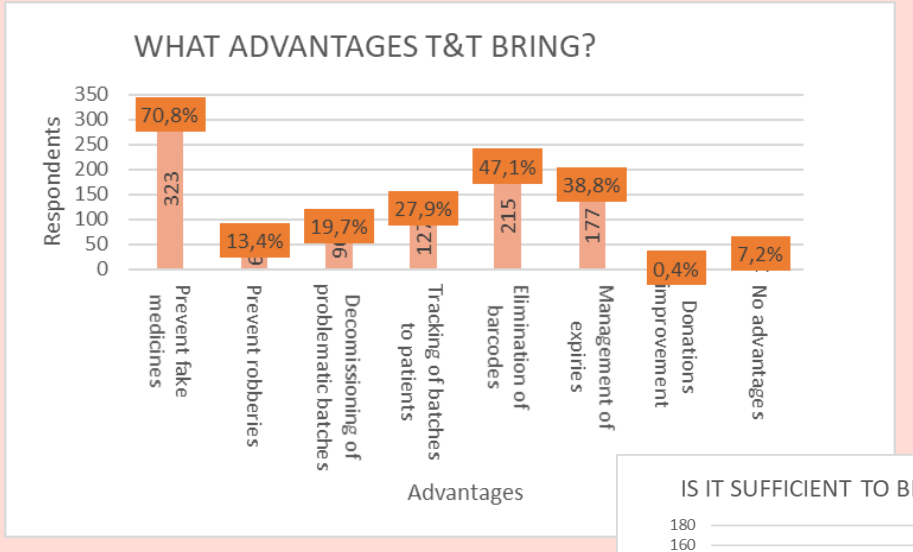


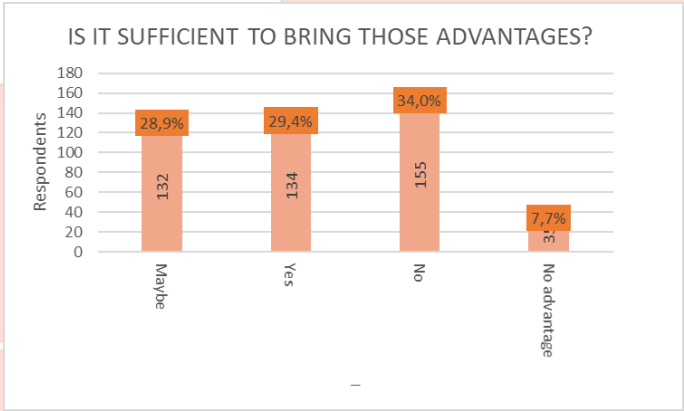




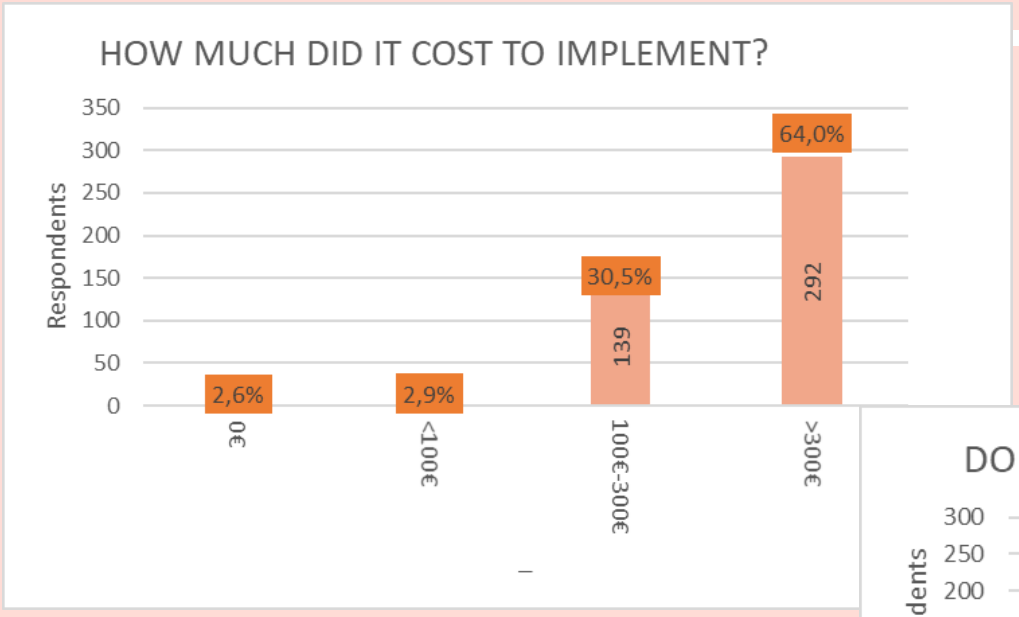


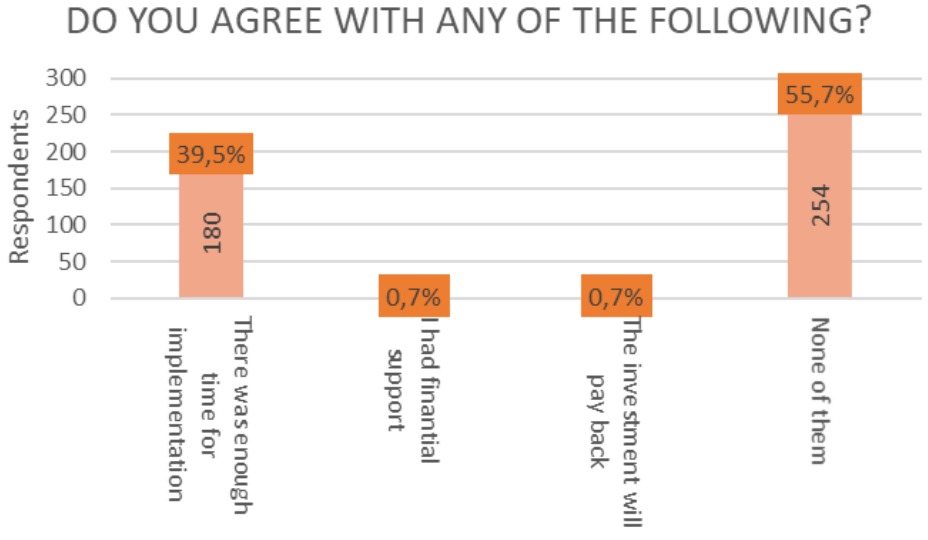
IMPROVEMENTS: VIEW OF PRACTITIONERS





IMPLEMENTATION





PRELIMINARY GENERAL CONCLUSIONS

Respondents: experienced community pharmacy practitioners

4,8% without problems: needs to be polished. Just launched

Well known by practitioners; informations and products

Advantages: fake medicines/ barcodes/ expiries

System insufficient for those advantages

Widely used: 23% decommission less than half packages

International complex project, with many stakeholders and stages.

It seems to be well accepted by community pharmacy practitioners.

It has different advantages; most importantly securing the supply chain of medicines.

IF IT HAS BEEN
DONE IN EUROPE
IT CAN BE
DONE IN ASIA

THANKS

Do you have any questions?

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Available at:

Jaime Acosta-Gómez