Pharmacists' warning systems on medicines shortages

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FIP-TPA Conference for the European Region
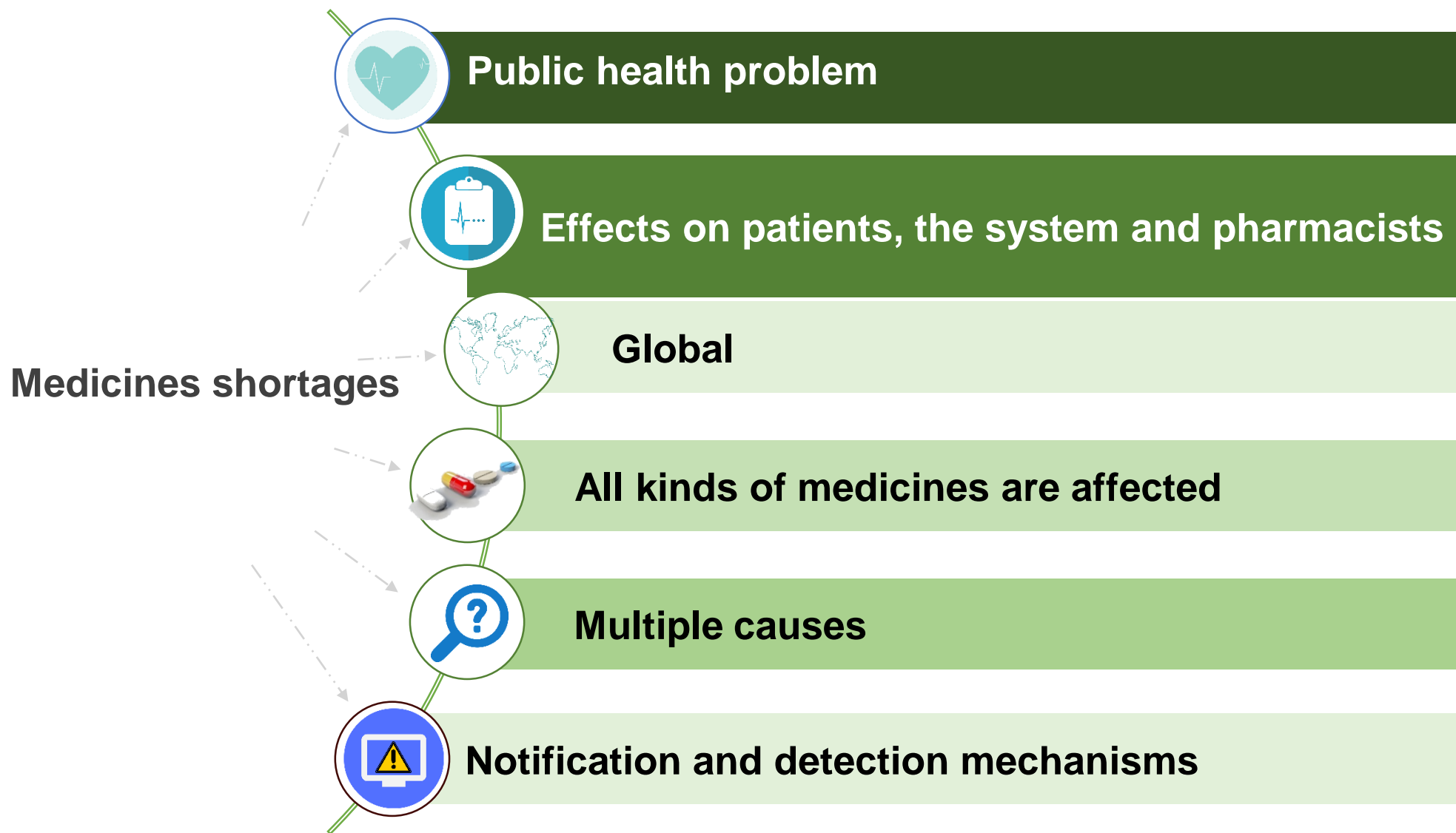
Ankara, 24th October 2019

01
Medicines shortages

Why?

Medicines shortages

- **Public health problem**
- **Effects on patients, the system and pharmacists**
- **Global**
- **All kinds of medicines are affected**
- **Multiple causes**
- **Notification and detection mechanisms**

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What do we need?

A system on detection and notification of medicines shortages

- Detect patient needs

- Reliable and agile information

- Early detection

- Cross border

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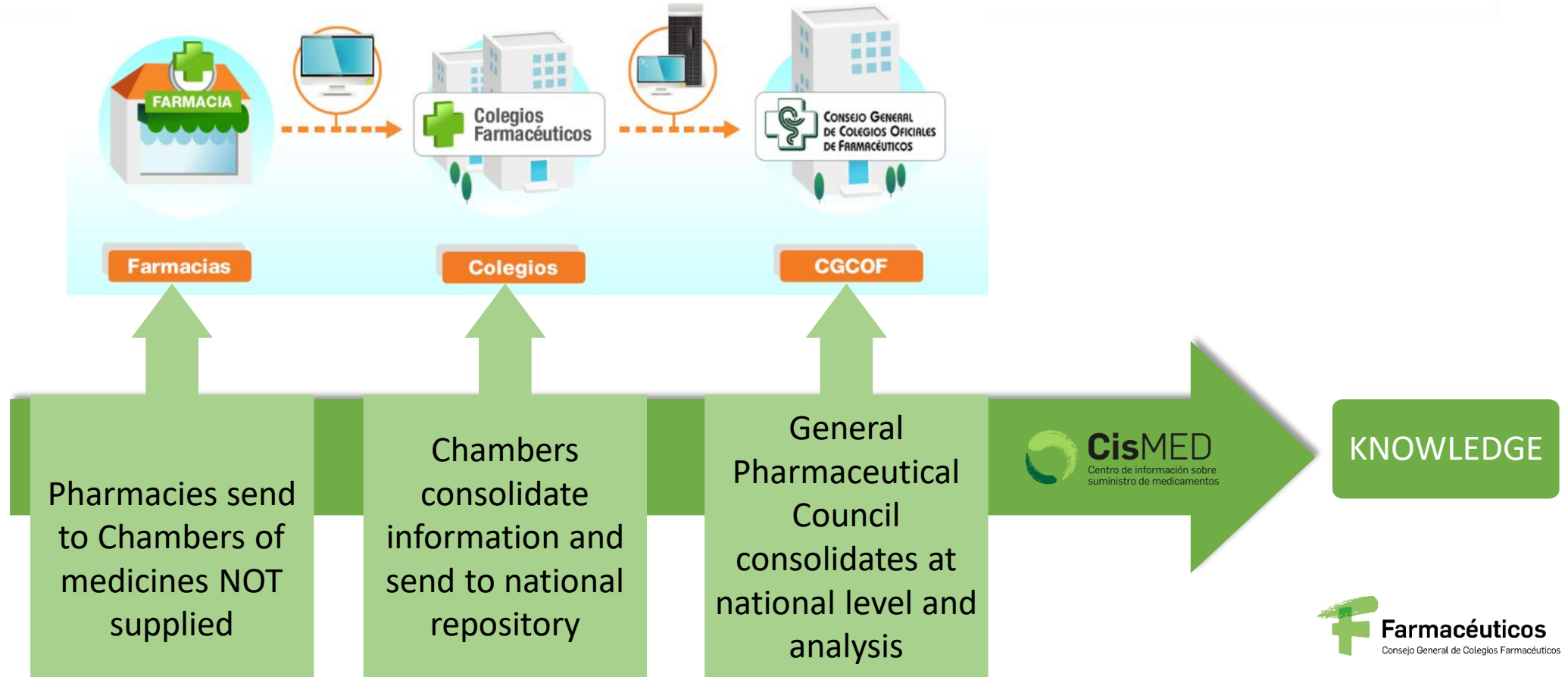Consejo General de Colegios Farmacéuticos

02
CISMED

Based on unmet pharmacy orders

CISMED is based on a communication infrastructure of pharmacies - provincial chambers- General Pharmaceutical Council of Spain

Pharmacies send to Chambers of medicines NOT supplied

Chambers consolidate information and send to national repository

General Pharmaceutical Council consolidates at national level and analysis

KNOWLEDGE

Simplicity
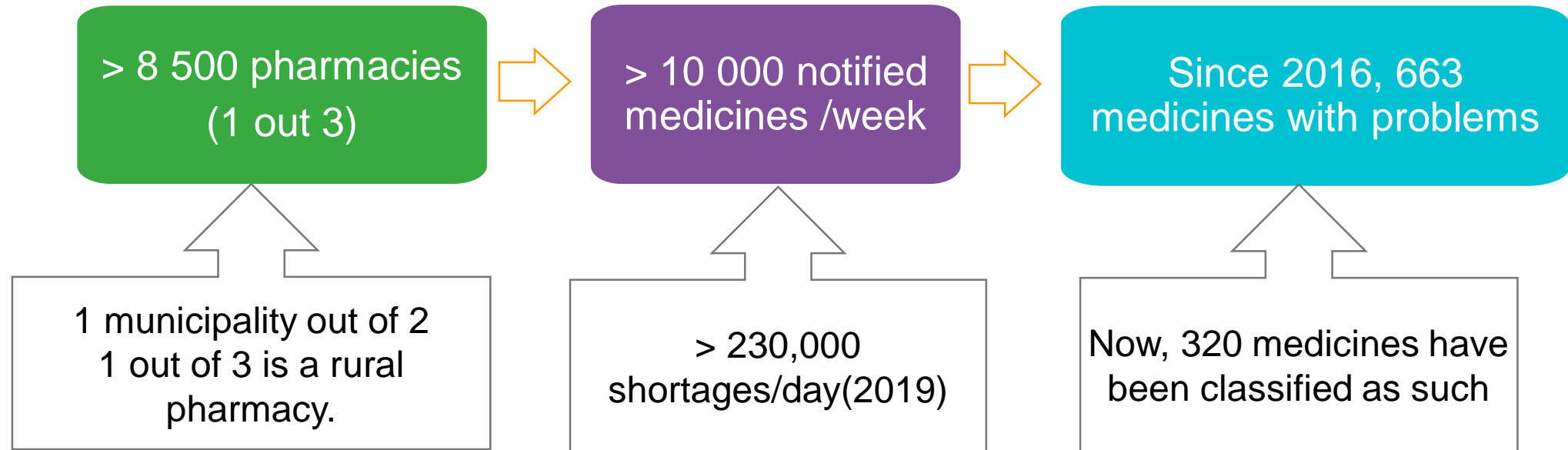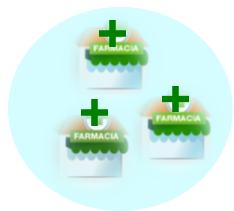
Type of information transmitted
-ID pharmacy
-National code
-Date of the unmet order
-Number of units not served

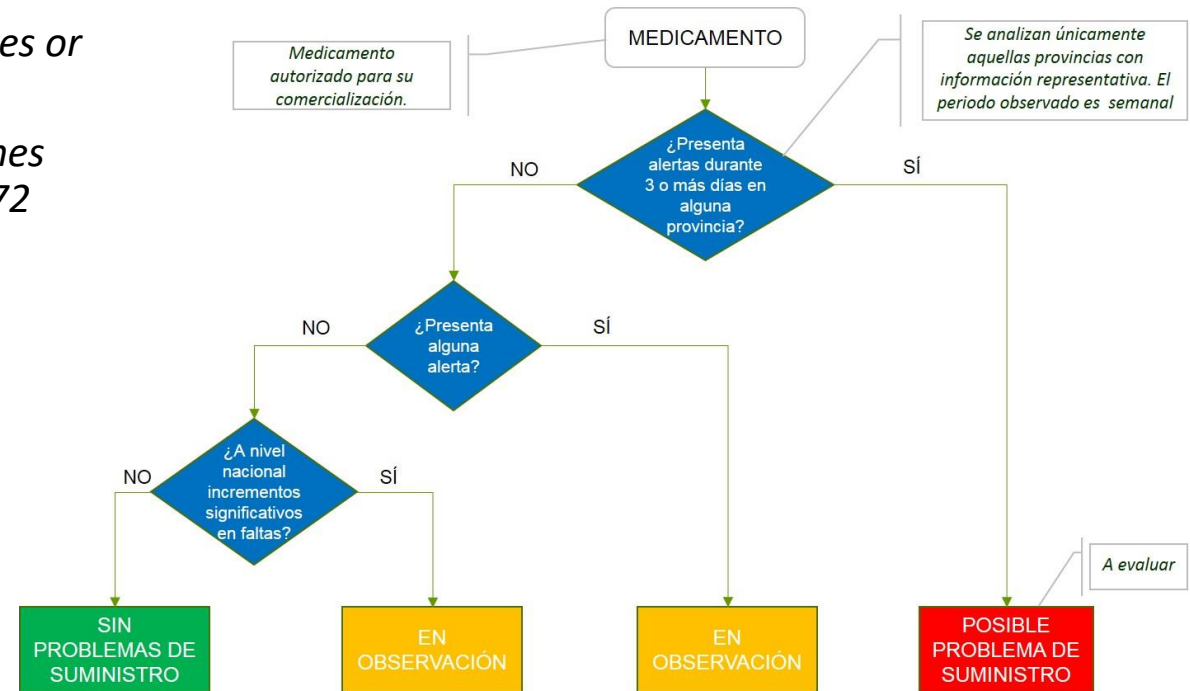**Easy adherence of pharmacies to the system:** consent form or web adherence

Automatic reporting

Effectiveness

> 8 500 pharmacies
(1 out 3)

> 10 000 notified
medicines /week

Since 2016, 663
medicines with problems

1 municipality out of 2
1 out of 3 is a rural
pharmacy.

> 230,000
shortages/day(2019)

Now, 320 medicines have
been classified as such

Given the potential impact on patients, it is important to collect all medicines shortages
reported by pharmacies, even if not all of them represent a supply problem

Analysis

- No definition of shortage at European level in quantitative terms

  - *In <u>Belgium</u>, a medicine is considered unavailable when the companies responsible for its marketing cannot deliver that medicine for an uninterrupted period of four days to pharmacies or distributors.*

  - *In <u>France</u> they describe as interruption of the supply of medicines when a pharmacy cannot dispense a drug to a patient within 72 hours or within a shorter time, depending on the treatment*

- Statistical analysis, comprising two dimensions
  - Provincial
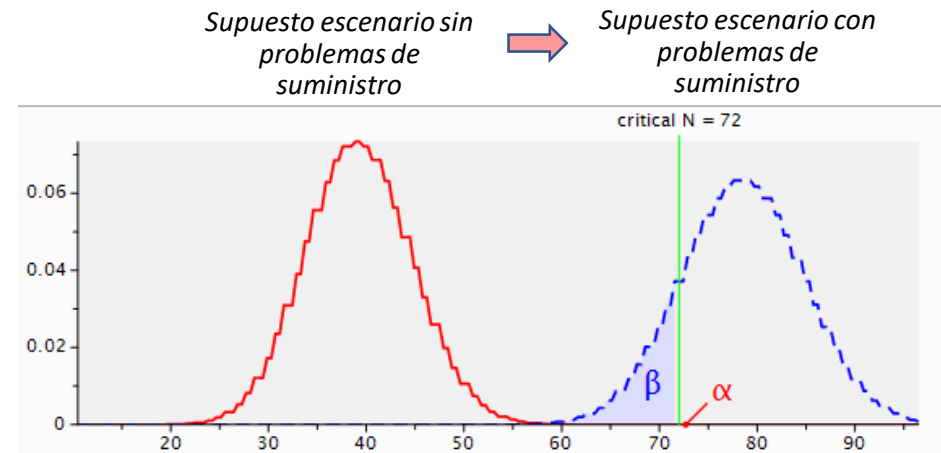 - National

- Categorisation of medicines

Examples of analysis

- Procedure at provincial level

Number of reporting pharmacies = 157 → Critical value= 72 (data week 4-10 March 2019)

TRANKIMAZIN RETARD 0.5 MG 30 COMPRIMIDOS LIBERACION PROLONGADA

DAY	Pharmacies with short supplies	State
LUNES	81	ALERT
MARTES	82	ALERT
MIÉRCOLES	76	ALERT
JUEVES	76	ALERT
VIERNES	80	ALERT
SÁBADO	66	NO ALERT
DOMINGO	3	NO ALERT
ESTADO FINAL	POSSIBLE SHORTAGE PROBLEM	

Supuesto escenario sin problemas de suministro → Supuesto escenario con problemas de suministro

critical N = 72

β α

α=Error tipo I. Probabilidad de concluir incorrectamente la existencia de problemas de suministro. Poder estadístico 1 − β = Probabilidad de concluir correctamente la existencia de problemas de suministro
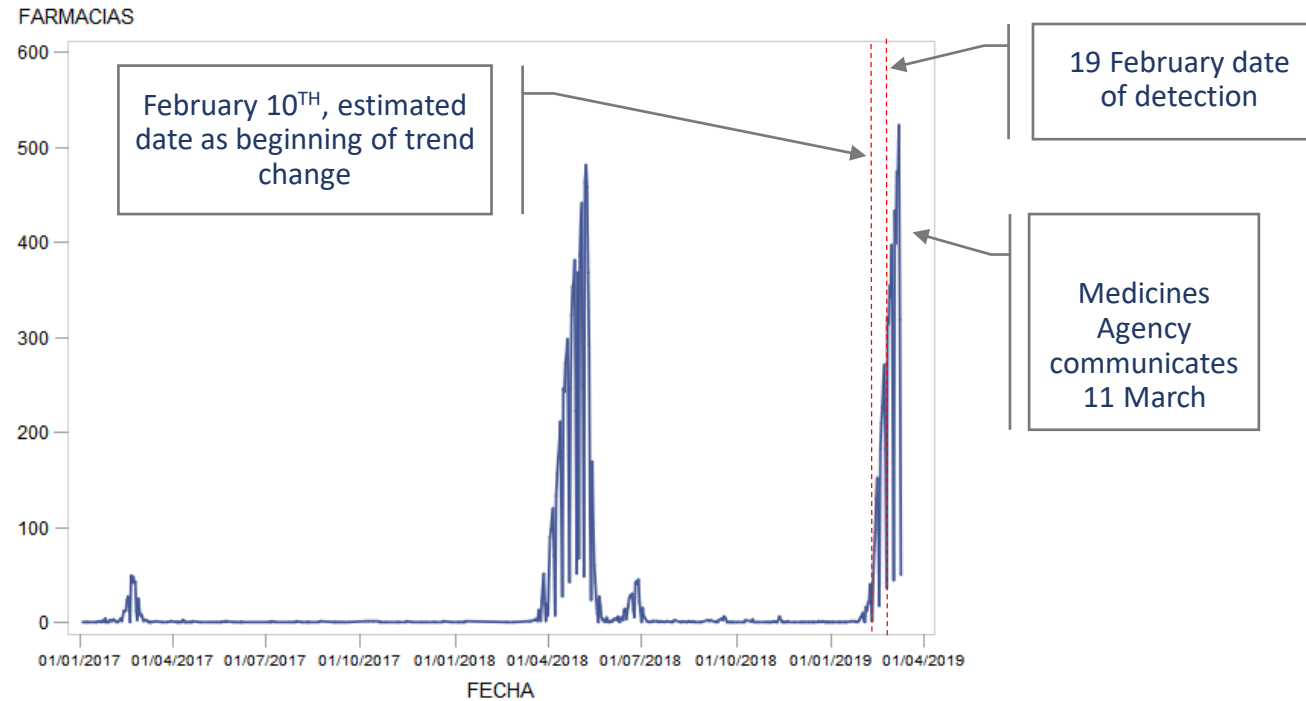
A statistical power analysis is used. Critical values may vary depending on the parameters used.

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Examples of analysis

- Procedure at National level

PROSCAR 5 MG 28 COMPRIMIDOS RECUBIERTOS. DATA UNTIL 10 MARCH 2019

CHANGE DETECTION MODEL

Sequential non-parametric model in which each data is evaluated deciding if it constitutes a significant increase with respect to the previous situation

February 10TH, estimated date as beginning of trend change

19 February date of detection

Medicines Agency communicates 11 March

FARMACIAS

FECHA

Results

- Categorisation of medicines (cont.)

  ☹ M. with possible shortage problems: medicines with alerts in at least one province during >=3 days during the week observed

  😐 M. under monitoring: medicines with alerts < 3 days in different provinces during the week observed, or nationwide, if in their historical evolution it has been detected recent significant increases in the number of pharmacies with short supplies
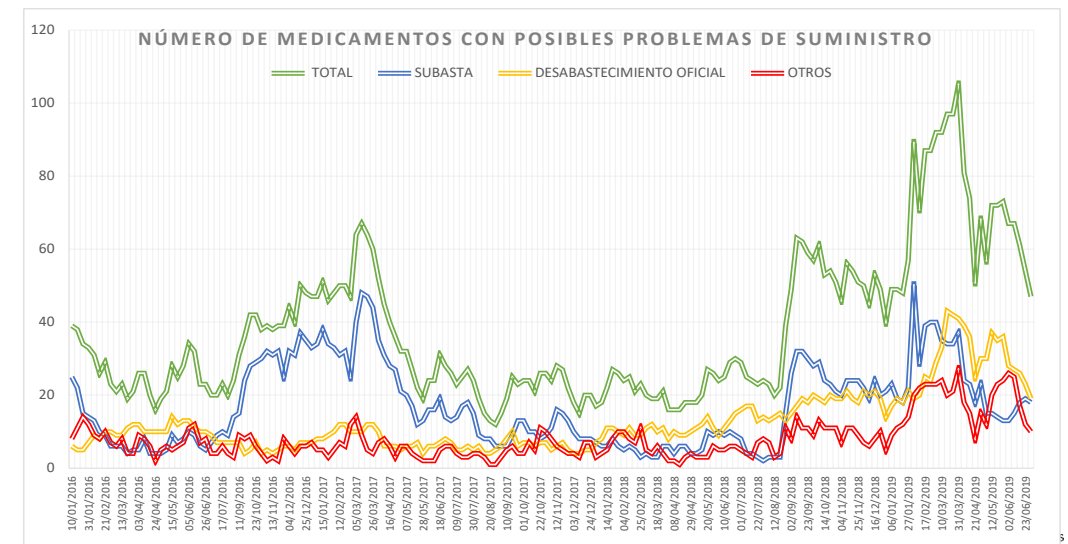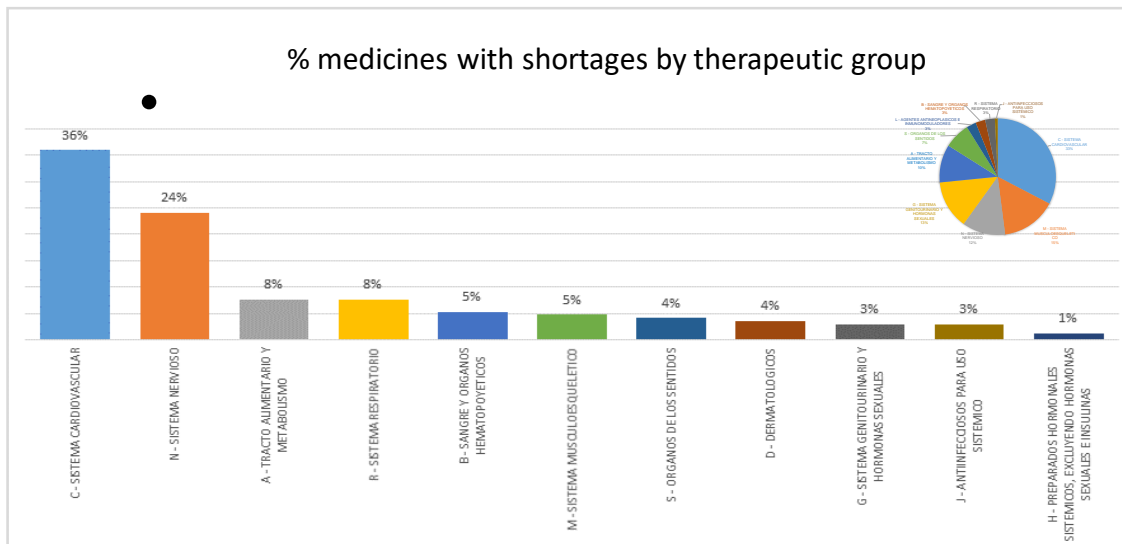
  😊 M. not in shortage

- Example medicines in shortage identified by CISMED before being notified by Medicines Agency:
  - *VITAMIN RHINOCUSI 12500 UI/G NASAL OINTMENT*
  - *CLEXANE 40 MG (4000 UI) 10 PRE-FILLED SYRINGES*
  - *FEBRECTAL INFANTS*
  - *APOCARD 100MG 60COMP*
  - *VARIARGIL 40 MG/ML ORAL DROPS*
  - *TERBASMIN TURBUHALER 500*
  - *DAILY LOETTE 100/20 MCG..*
  - *TEVETENS PLUS 600/12.5 MG*

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Access to information

- **Reports**
  - Include: n. of pharmacies with shortages per medicine, provinces, medicine description, whether shortage reported by AEMPS or not, type of medicine: substitutable or non-substitutable, active ingredients of the medicine, therapeutic group, prices etc.
  - + 1,000 monthly reports (pharmacists chambers, Ministry of Health and Medicines Agency and other NCAs)
  - Shortages published weekly on the General Council website

% medicines with shortages by therapeutic group

NÚMERO DE MEDICAMENTOS CON POSIBLES PROBLEMAS DE SUMINISTRO

Access to information

- **Portal web**

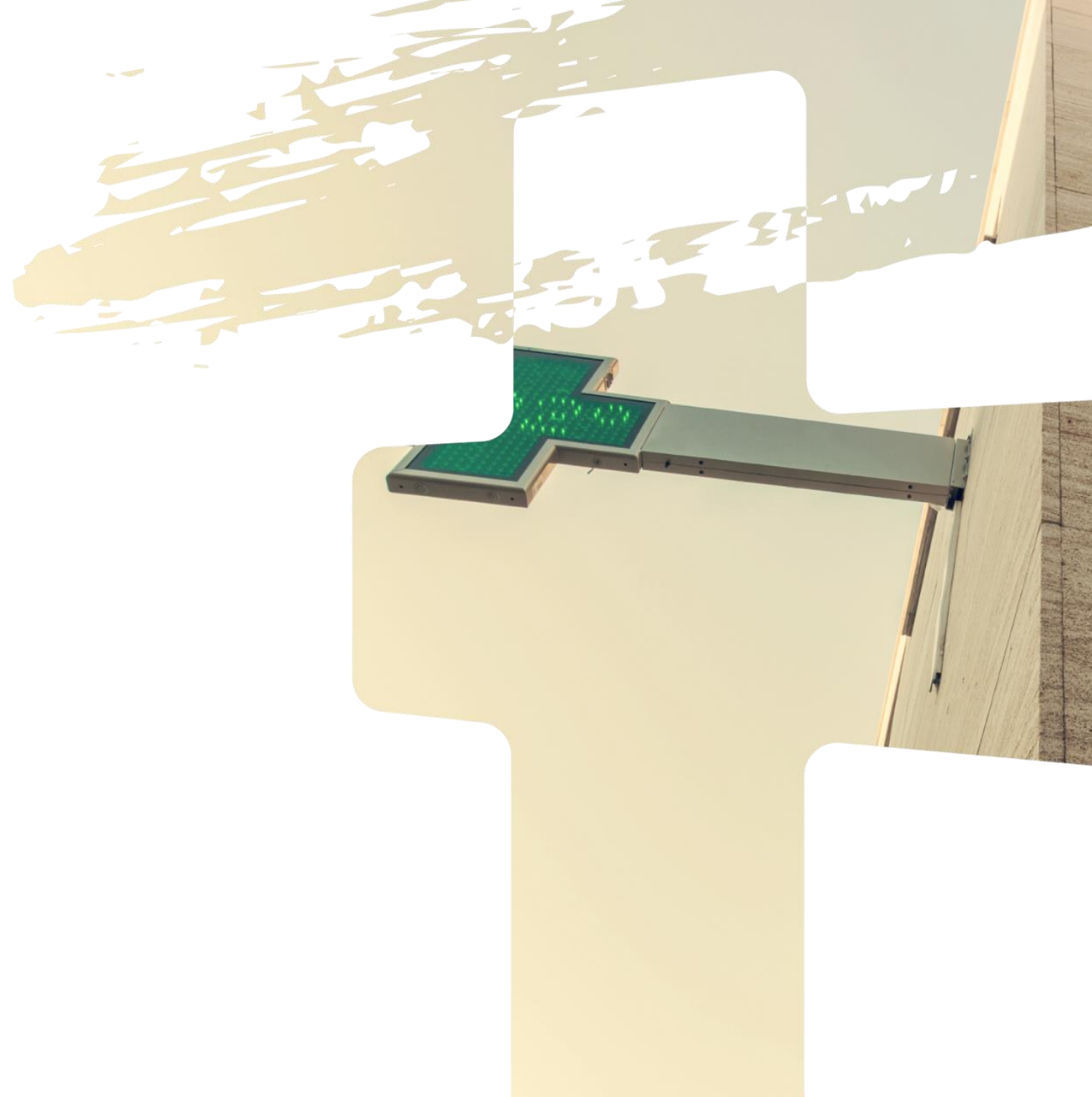|	Users
☐	Health professionals and patients
☐	Pharmacist Chambers
☐	Medicines Agency, Ministry, NCAs

	¿What would it allow?
☐	Make queries
☐	Generate and download yparameterizable reports
☐	Access to information customised by users profile

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03
Next steps

Next steps

- Improve early detection tools (*machine learning, etc*)

- Collaboration with Spanish Medicines Agency

- Collaboration with other stakeholders

- Scaling up at EU level: **European Project**
  - France, Italy, Portugal and Spain
  - in collaboration with the Medicines Agency of Spain
  - Application for EU funding in August -> Project selected

APPROVED

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CONCLUSIONS

- **Pharmacists** are **key** to notify shortages and can help risk mitigation management through an early detection

- For this, we need systems where **information** is **reliable**, in **real time**, and allows for efficient management

- The system should incorporate **predictive tools** to allow for preventive measures

- In **collaboration** with authorities and rest of supply chain stakeholders

THANK YOU!!

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