EMA
EUROPEAN MEDICINES AGENCY

# Medicines Safety

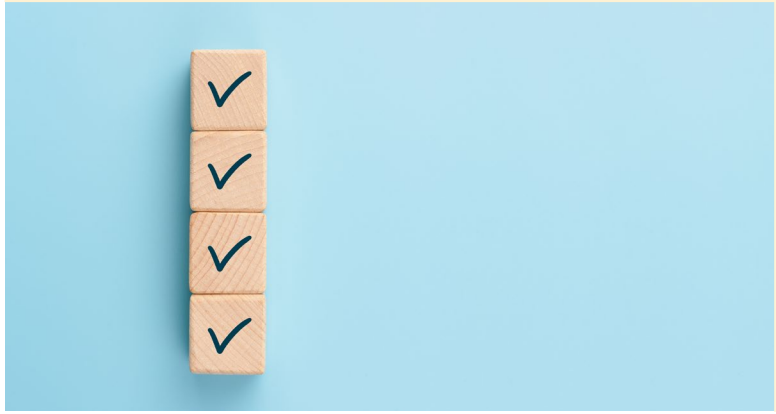
## How we monitor the safety of medicines

# Proactive safety monitoring

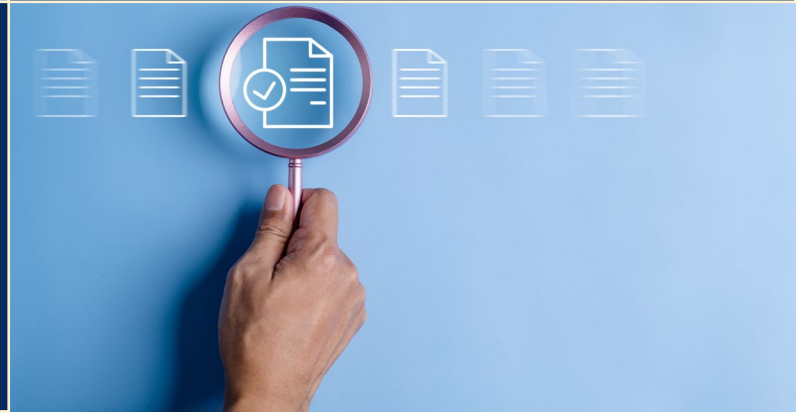
When a company seeks approval:

- submits detailed data on the medicine's safety;
- further studies can be requested.

Information on side effects can be found in the medicine's package leaflet

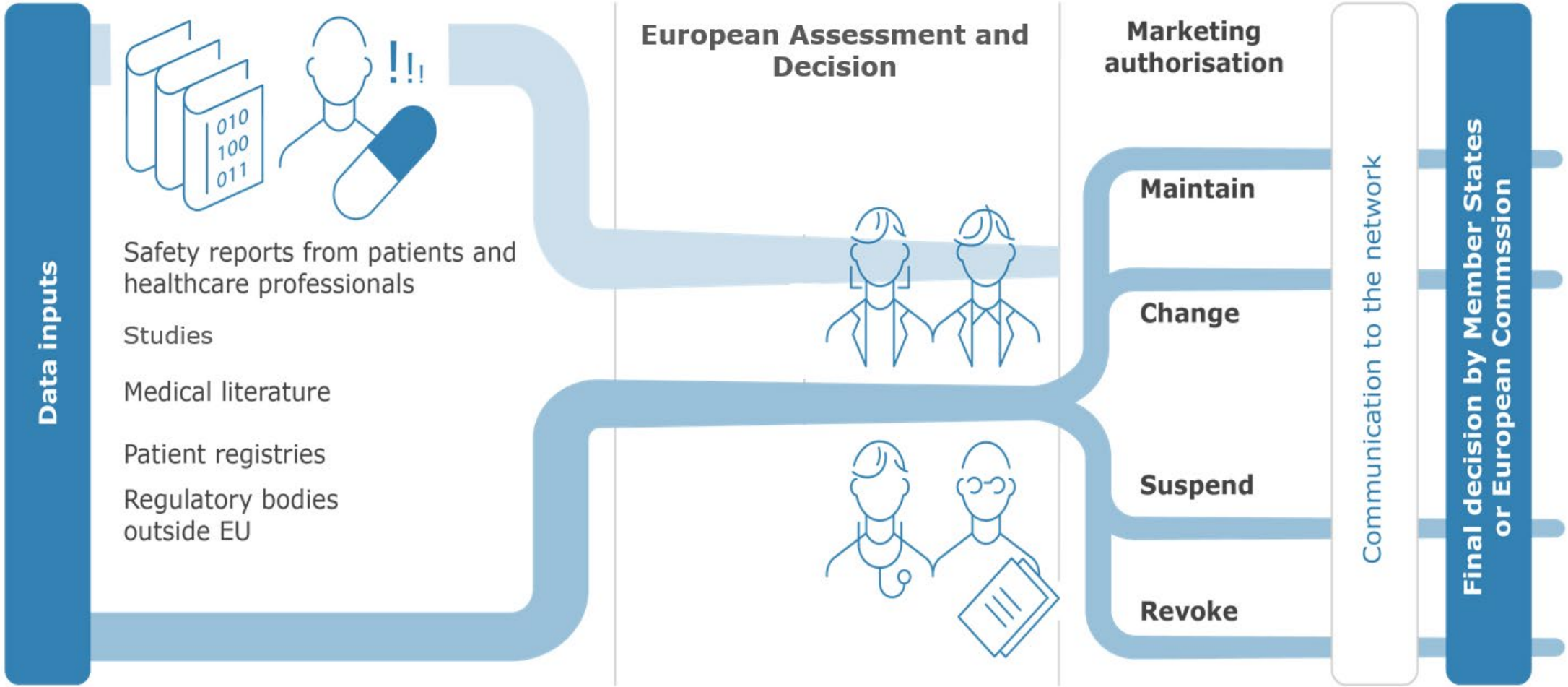


Pharmacovigilance allows for the detection, assessment, understanding and prevention of side effects.



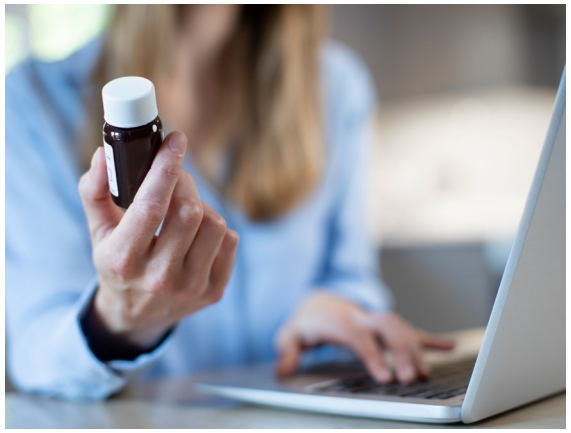
# Monitoring the safety of medicines across their lifecycle

https://youtu.be/LrWw2X97yf8



# Who can report side effects?

HEALTHCARE PROFESSIONALS



PATIENTS

CARERS

By reporting side effects, you can help medicines regulators learn more about the medicine and how it should be used to reduce its side effects.

**Did you know?**
In the Netherlands, you can report side effects to the bijwerkingencentrum Lareb (Netherlands Pharmacovigilance Centre Lareb) at www.lareb.nl

# How EMA ensures transparency

## COLLECTION & ASSESSMENT

Data is collected in a centralised safety database

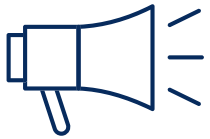
Public access in www.adrreports.eu

Annual report

## DECISION & ACTION

Scientific meetings agendas, minutes and highlights

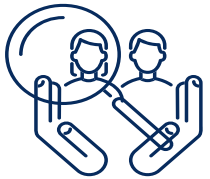
Assessment outcomes



## COMMUNICATION

Product Information, assessment history

Public Health Communications



## RISK MINIMISATION & MONITORING

Risk Management Plans

Studies conducted by EMA

Direct Healthcare Professional Communications

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# Thank you.

## Send a question to the European Medicines Agency

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