# PANORAMA OF ACTIONS PATIENT ORGANISATIONS CAN TAKE IN PHARMACOVIGILANCE

EURORDIS-Summer school 2017

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# Pharmacovigilance as a close watch on the medicines we take

## Whistle blowers

- Reporting ADRs

## Source of information

- Collecting data from our members

## Research partners

- Are the risk minimisation measures effective? accepted?

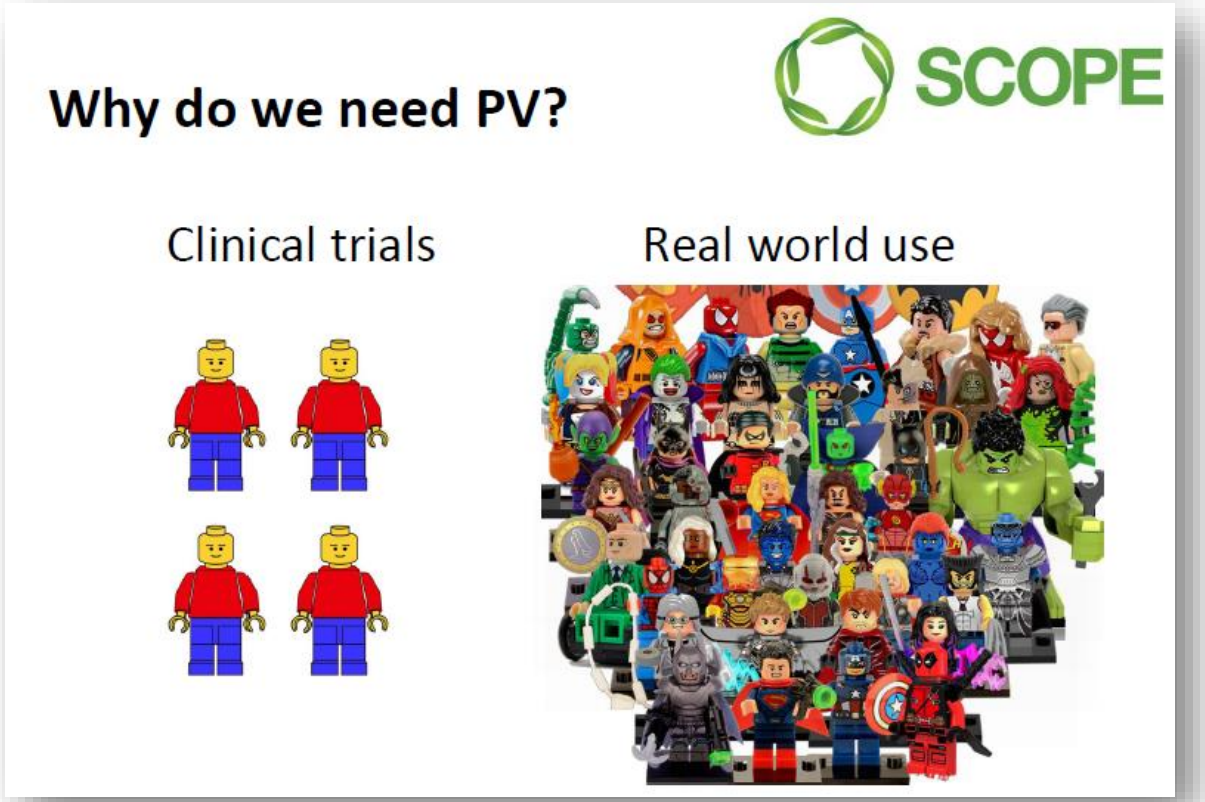
## Information loop

- 2-way communication, awareness campaigns

## Testers

- Are the messages understood? Is benefit/risk clearly explained?

# Why is it needed?
# Kendal Harrison, MHRA
## 22nd March 2017 , EURORDIS-SCOPE Pharmacovigilance training



# A look back

SCOPE

EMA Committees:

- CHMP – centralised drugs
- CMDh – MR/DC drugs
- PRAC - PV
- COMP - Orphan
- HMPC - herbals
- CAT – Advanced therapies
- PDCO - Paediatric

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

<1950s

Late 1950s/early 1960s

1963

1975

1978

1990

1995

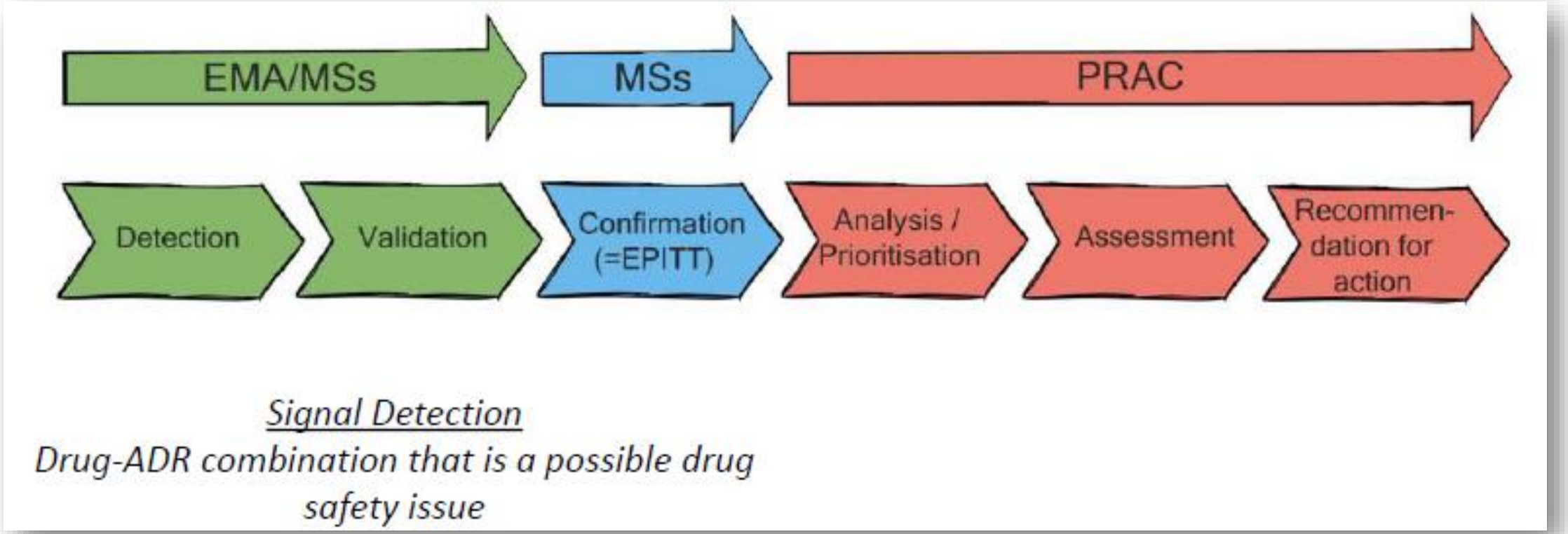
?


MHRA
Regulating Medicines and Medical Devices

FDA

Uppsala Monitoring Centre

ICH
harmonisation for better health



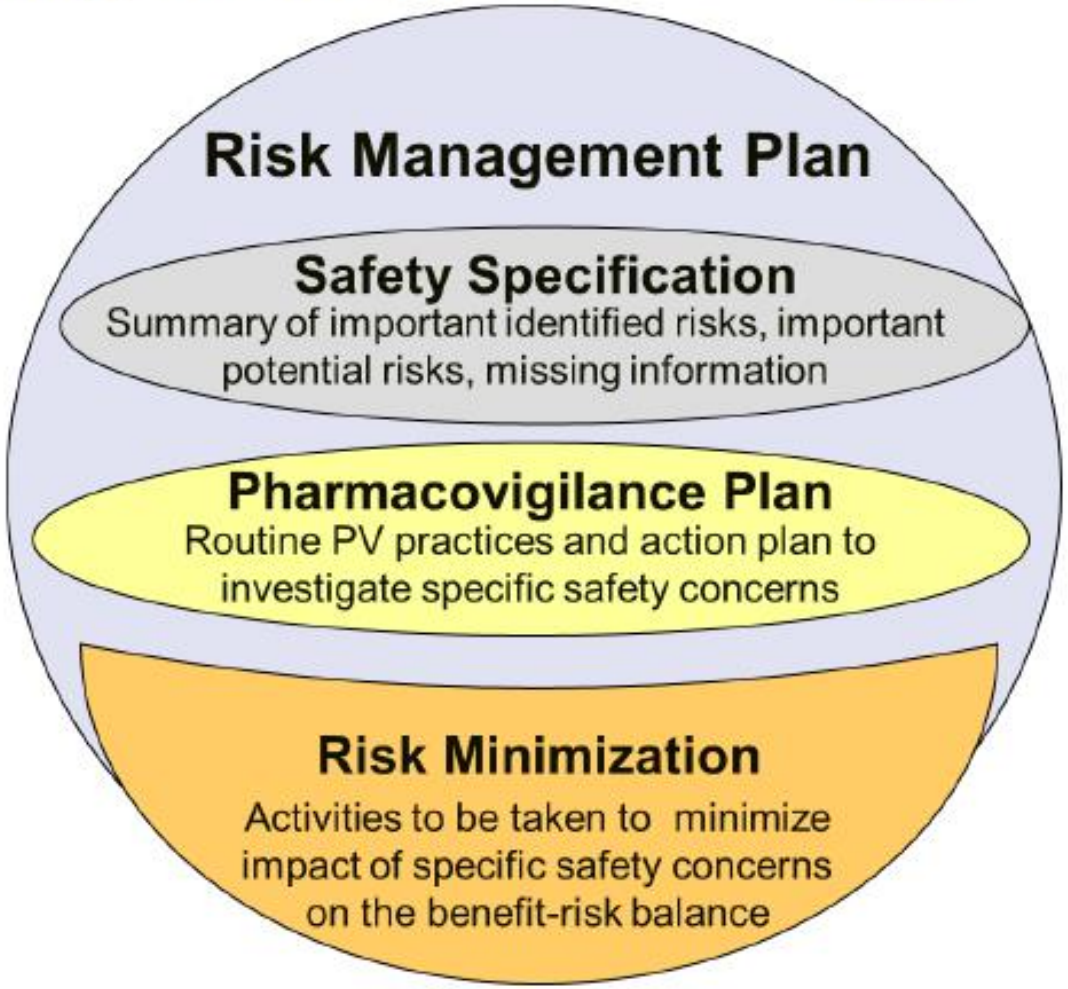

*Signal Detection*

*Drug-ADR combination that is a possible drug safety issue*

# Regulatory action options

- Update product information
  - Listed side effects
  - Restrict use – Contraindications, reduce dose
  - Risk management
- Drug withdrawal, rarely

# Risk Management Plans



# PASS/PAES studies

- Can be voluntary or imposed as a condition of MA approval
- Can be clinical trials or a non-interventional study

Post-Authorisation Safety Study (PASS)

- Enhance safety knowledge
- E.g. real world data in special populations

Post-Authorisation Efficacy Studies (PAESs)

- Every day use efficacy
- Few to date

Non-interventional study details published on the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) website:
http://www.encepp.eu/encepp_studies/indexRegister.shtml

Clinical trials: https://www.clinicaltrialsregister.eu/

# Risk Management Plans

- Applications for **all** new MA (including generics)
  - New active substance
  - Biologics/Biosimilars
  - New indications – including extension to a different population
  - New route of administration/formulation
- Significant change to an existing marketing authorisation
- Reclassification application (e.g. POM to Pharmacy-only)
- Emerging safety issues, affecting the risk-benefit balance

RMP guidance:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000360.jsp

Search RMP or EPAR:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/landing/epar_search.jsp&mid=WC0b01ac058001d124

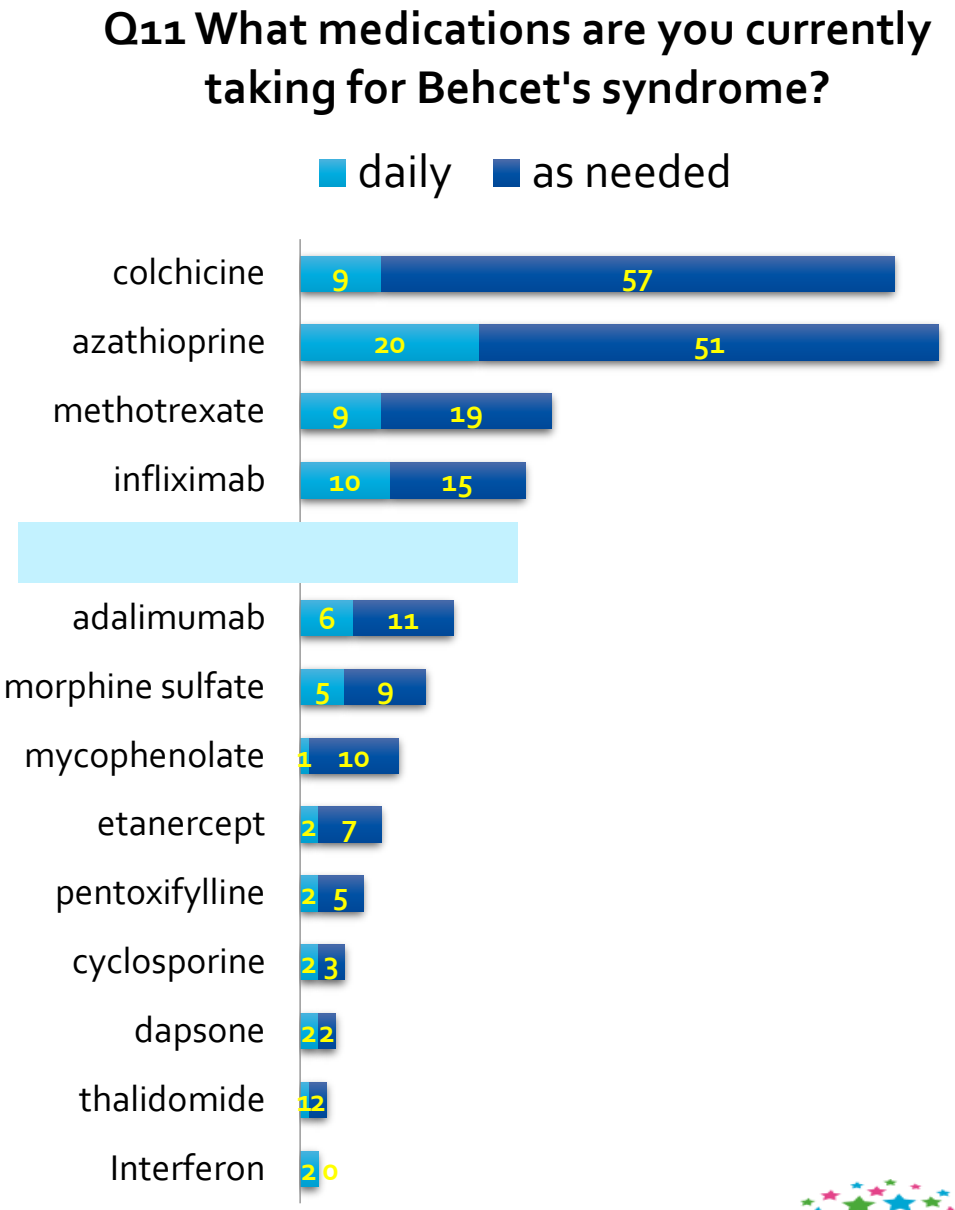
Example of a RMP summary (Adempas, HTAP)
http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Risk-management-plan_summary/human/002737/WC500162588.pdf

# Behcet's syndrome community

## map @ 3 months: 900/1348 patients indicated their location

# From our members

- Precious information that could generate knowledge
- If collected in a scientific way, and in consultation with pharmacovigilance experts to teach us how to best do this
- Here:
  - 194 patients with Behcet's syndrome described the treatments they take
  - None of them is approved for Behcet
  - Which tool could we propose to explore the b/r of these off-label use of medicines?







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# Which actions to engage patients in pharmacovigilance?

- Communication campaigns: e.g. ▼, safety issues alerts, SCOPE Awareness week, Take & Tell…
- Award of the most informative patient ADR report of the year
- National conference on pharmacovigilance: NCA, patients' and consumers' organisations (PCO), other stakeholders
- Sharing DHCP letters
- Specific calls for projects to PCOs on pharmacovigilance
- Patients as members of the national/European PRAC
- Consultation on Package leaflet, education materials
- Involvement of PCOs in the design of new tools for spontaneous ADR reporting
- Detailed review, evaluation, follow up and feedback, case by case
- Verbal and email updates on topical issues, as appropriate…
- Collect information from your member on shortages of medicines
- …

# French regulatory agency (ANSM) call for projects to patients' organisations

video

- 32 projects funded for a total of 809 410 €
  - To facilitate patient reporting, to stimulate and support initiatives aiming at reducing the risks related to health products
- In 2012 : 9 projects selected, total grants: 260 000 euros
  - Tools to help patients with MS to report adverse reactions to drugs or devices (35 000€)
  - Self-reporting of any health events after exposure to diethylstilbestrol  until 3rd generation (40 000€)
- In 2013 : 10 projects, 230 500 €
  - Internet tools and videos to report ADRs in hemophilia (neutralizing Ab) (24 000€)
  - MRIS, help line supported to take calls about ADRs (15 000€)
  - Surveillance for women taking hormonal therapy after breast cancer (30 000€)
- In 2014 : 7 projects, 165 300 €
  - 23 projects received, 22 eligible
  - Launch of reporting tools for drug associated behaviour changes in Parkinson (20 000€)
- In 2015: 6 projects, 149 110 €
  - Analysis of social media discussions on medicines used by kidney patients, during dialysis or after transplant (35 000 €)
  - Bone marrow transplantation (19 000 €)

# Building your pharmacovigilance expertise

## Vis à vis your members/peers

- When renewing membership, survey your members to learn more on their treatment (all the ones they can use, including off-label)
- Explain the signification of ▼ in package leaflet
- Advertise the importance to report suspected ADRs

## Vis à vis your national competent authority

- Test the online reporting tool in your country. Feedback to your NCA
- Review useful ADR reports with your NCA experts
- Review and discuss risk communication channels in your country. Do they work?

## Vis à vis EMA

- Review Risk Management Plan summaries for medicines of interest to you. Feasability? Constrains?
- Register to EMA RSS feeds/monthly highlights
- See PRAC agendas / minutes

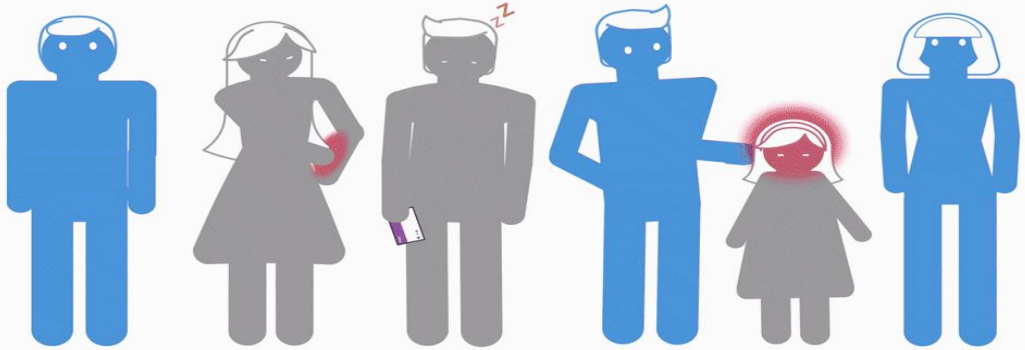
# To come

| | |
|---|---|
| PO contact person for pharmacovigilance | • The "QPPV" in patients' organisations |
| Package leaflet, education materials | • Graphic visualisation of risks, benefit/risks (post PROTECT) |
| Patients' social media analysis | • Web-RADR, ADR-Prism, Vigi4Med… |
| Public hearings | • At EU level and their national version, or national topics |
| Other research instruments | • Direct to patient pharmacovigilance (e.g. Pregabalin study, PROTECT (pregnancy)) |
| Help Lines | • Support patients' help line participating in ADR reporting |

# The contact person for pharmacovigilance

- NCA could ask request patients' organisations to appoint an official contact person for pharmacovigilance who would:
  - Be trained on how pharmacovigilance is organised in Europe and in Member State
  - Receive all safety alerts and/or DHCP and decide which ones are of interest for their members
  - Be informed on national / international initiatives on pharmacovigilance
  - Identify available communication tools to increase awareness (Take & Tell, Awareness week video…)
  - Be consulted when information needs to be prepared (e.g. safety referrals)
  - Receive questions from members, analyse the organisation' social media, collect spontaneous ADRs….

# Engaging patients in pharmacovigilance!



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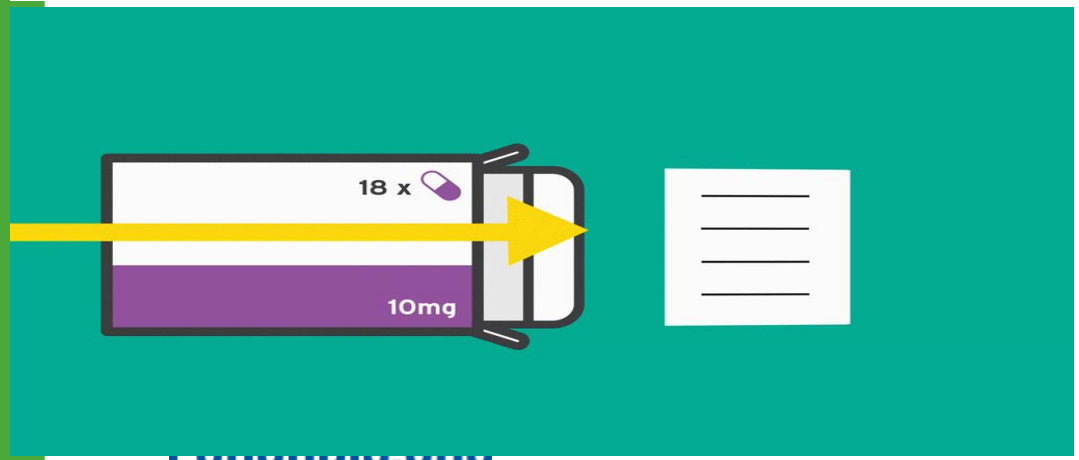
SCOPE




SCOPE

# Suspected side effect?

# Reporting helps

Mitul Jadeja

SCOPE EURODIS PV training

# Reporting is improving