

Pharmacovigilance legislation

**present situation and perspectives
for polish patients**

About ECPC:

- Established in 2003;
- Only European organization governed by cancer patient groups;
- 340 members in 42 countries;
- All age groups, ethnic communities, cancer types;
- Full members European patient groups governed by patients, for patients.

ECPC Mission:

Equip, enable and empower our members to actively advocate for equality in access to front line cancer care and to engage in all aspects of cancer care, treatment and research locally, nationally and internationally.

“Nothing about us without us”

ECPC Activities:

- Patient education
- Patient involvement
- Health and cancer care policy
- EU funded projects
- Research
- Working groups

Pharmacovigilance in Poland

The past

- Only professionals (doctors and pharmacists) authorized to report adverse drug reactions,
- Lack of information for patients,
- Low public awareness on pharmacovigilance among polish patients,
- Unreliable patient – doctor communication,
- Low level of awareness on adverse drug reaction reporting among primary care physicians.

Pharmacovigilance in Poland

The present

- The adoption of Directive 84/2010 is still in progress,
- According to current regulations patients are still not allowed to report directly adverse drug reactions,
- Step forward: electronic forms available for reporting adverse drug reactions,
- Step backward: patients are not informed by professionals of electronic forms existence.

Pharmacovigilance in Poland

The present

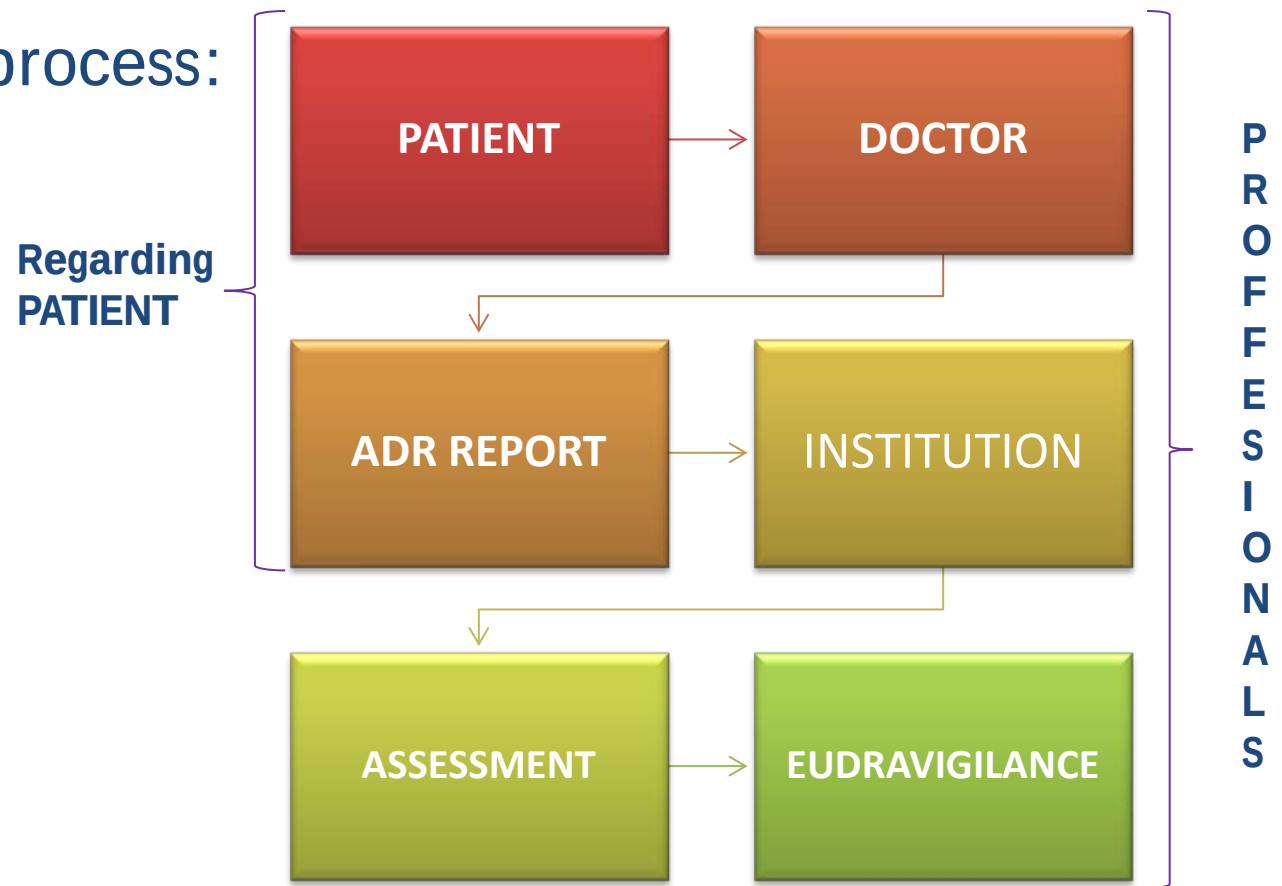
First is the cycle:



Pharmacovigilance in Poland

The present

Second is the process:



Pharmacovigilance in Poland

The present

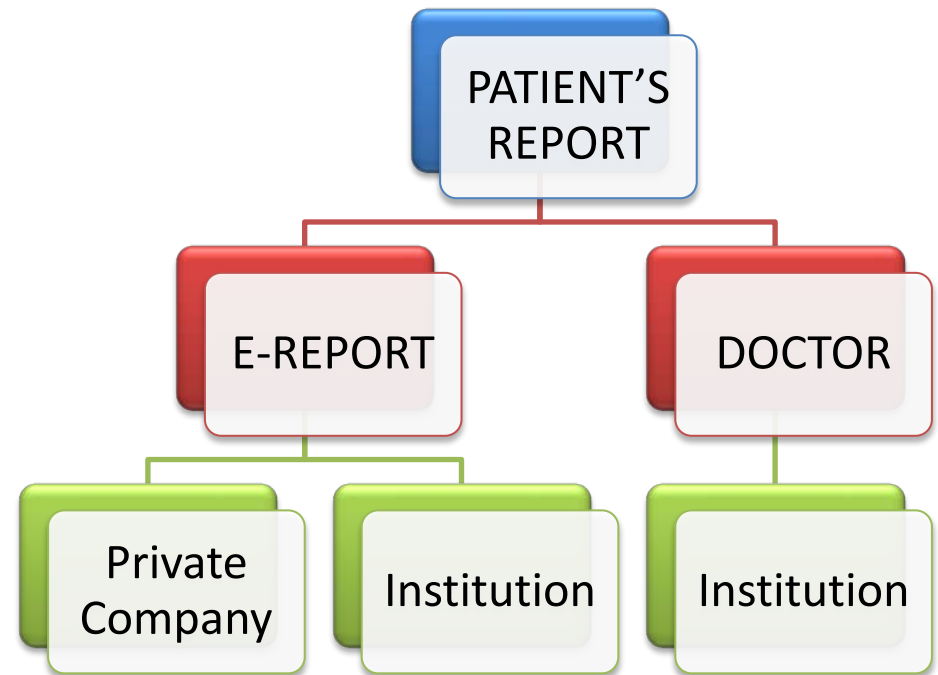
Discrepancies:

Institution:

Pharmacovigilance Department
in The Office for Registration
of Medicinal Products, Medical
Devices and Biocidal Products

Private companies:

- Pharma,
- Consulting companies,
- Law firms,
- other



Pharmacovigilance in Poland

The present

Discrepancies:

- No communication between private companies and the Pharmacovigilance Department,
- Professionals are obliged to report each ADR case but it's unknown if the report is directed to the Pharmacovigilance Department or private company,
- The patient's situation with reported ADR is the same: „thank you for your cooperation”.

Pharmacovigilance in Poland

The present

Pharmacovigilance Department Data for 2012:

- 1144 ADR reports from professionals,
- 1534 reports on adverse post-vaccination reactions from Sanitary-Epidemiological Stations,
- 4539 ADR reports from responsible entities.

Pharmacovigilance in Poland

The present

Patient's Data:

(random test, 36 people, aged 18 – 60, time: last three weeks)

- Have you ever been informed by a doctor of ADR reporting possibility?
- Have you ever been informed by a pharmacist of ADR reporting possibility?
- Have you heard about new pharmacovigilance legislation? (possibility of direct ADR reporting)

Three possible answers:



YES



NO



DO NOT REMEMBER

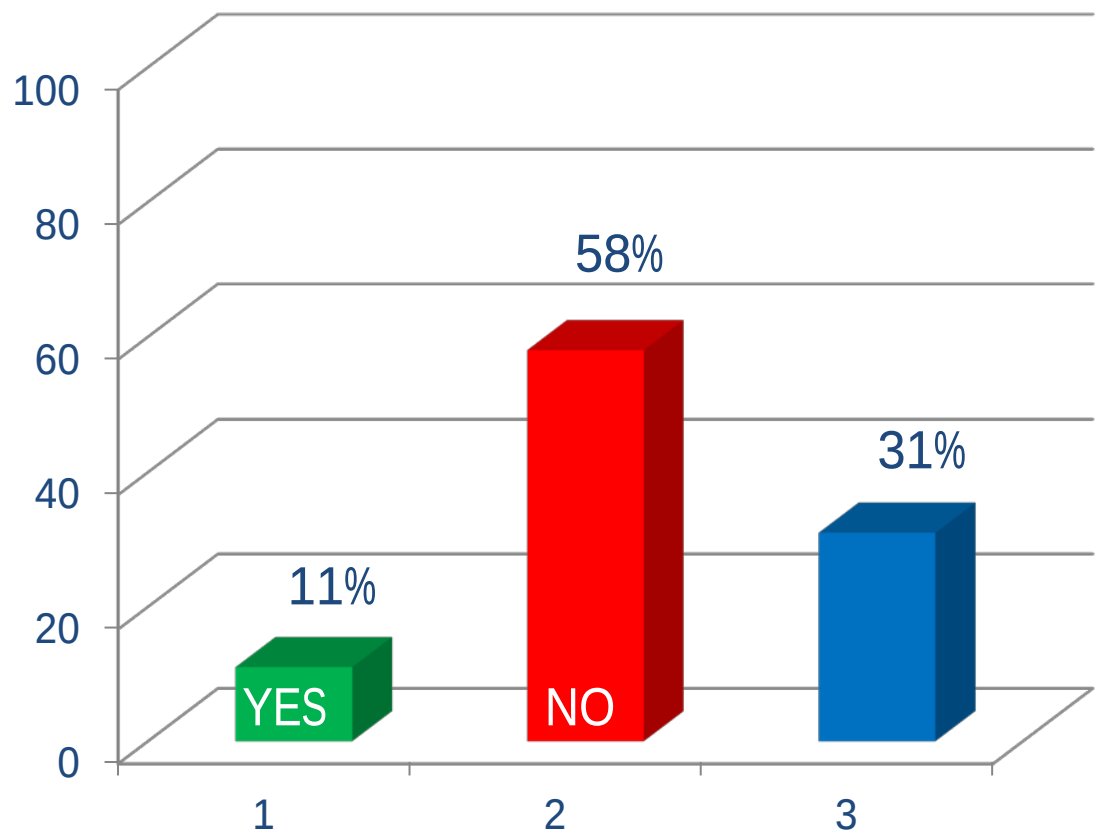
Pharmacovigilance in Poland

The present

Patient's Data:

(random test,
36 people,
aged 18 - 60)

- Have you ever been informed by a doctor of ADR reporting possibility?



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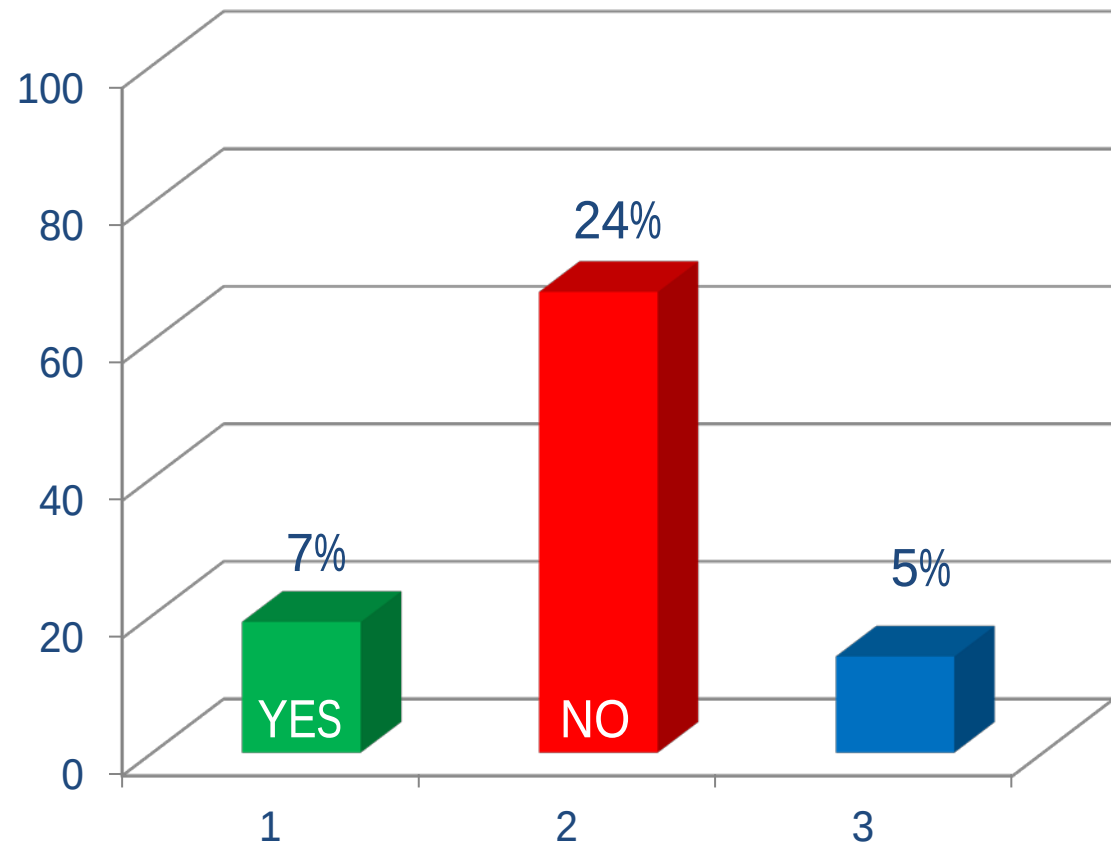
Pharmacovigilance in Poland

The present

Patient's Data:

(random test,
36 people,
aged 18 - 60)

- Have you ever been informed by a pharmacist of ADR reporting possibility?



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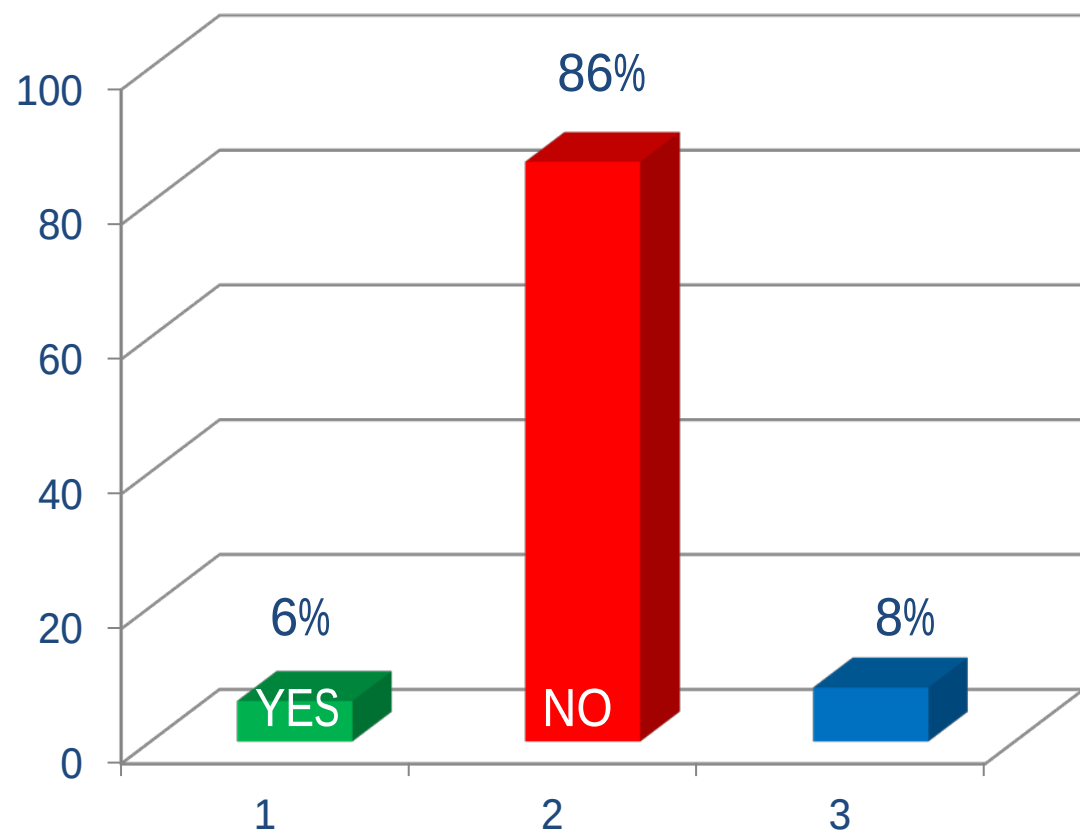
Pharmacovigilance in Poland

The present

Patient's Data:

(random test,
36 people,
aged 18 - 60)

- Have you heard about new pharmacovigilance legislation?



Pharmacovigilance in Poland

Perspectives

- Implementation of Directive 84/2010,
- Clear regulations,
- Education of patients,
- Mandatory physicians education,
- Cooperation establishment between patient organizations and The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products in order to organize a public campaign on pharmacovigilance regulations and patients' rights to report ADRs.

Pharmacovigilance in Poland

The impression

- Patients are aware about their right to report any ADRs. However, they do not know how, when and to whom.
- The greater patient's awareness, the more efficient and effective treatment.

Thank you for your attention!

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ECPC Board Member



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