EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Pharmacovigilance

Joint plenary of PCWP and HCPWP: September 2019

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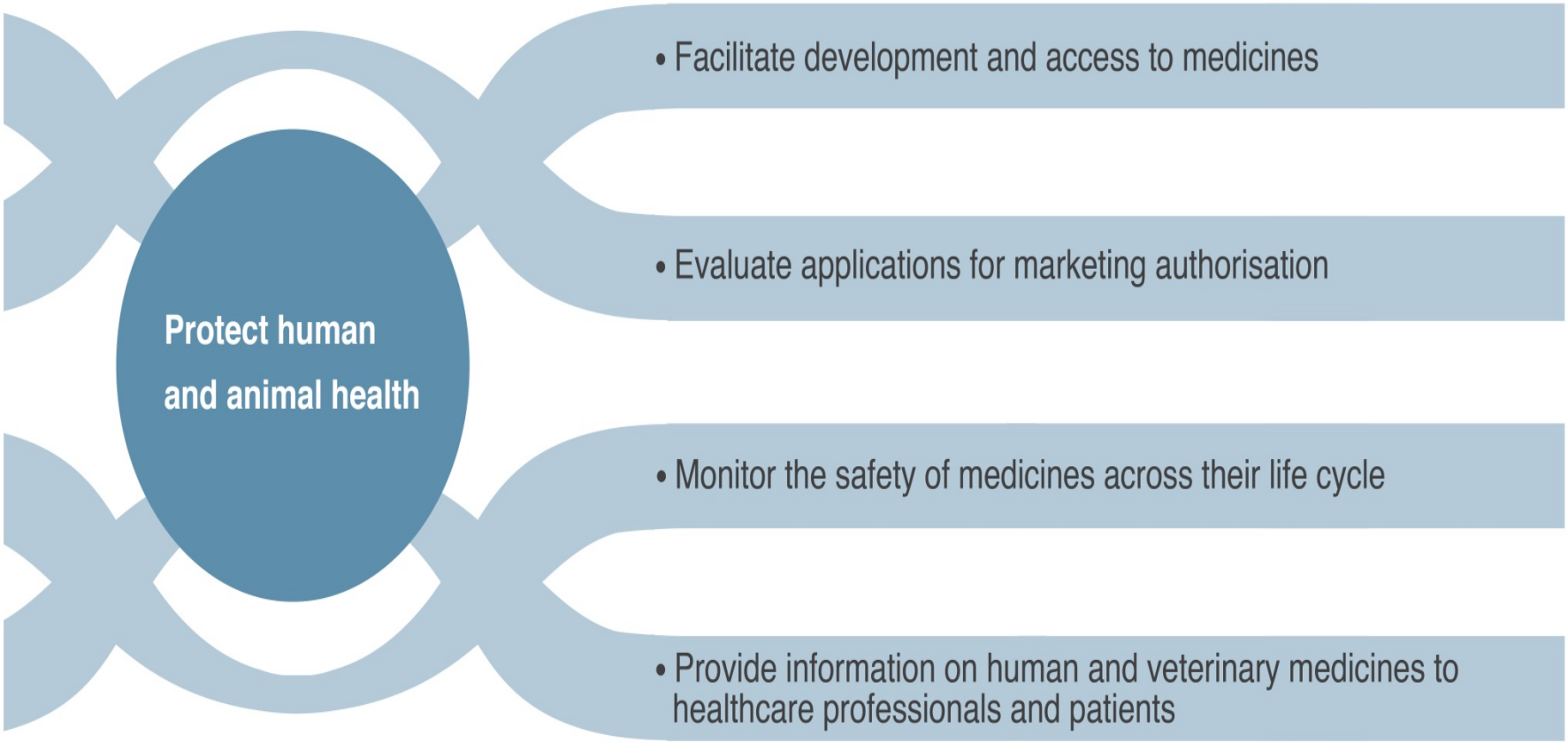
An agency of the European Union

What do we do?


Protect human and animal health
• Facilitate development and access to medicines
• Evaluate applications for marketing authorisation
• Monitor the safety of medicines across their life cycle
• Provide information on human and veterinary medicines to healthcare professionals and patients

Pharmacovigilance

WHO definition: “the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.”

- Estimated 197,000 deaths per year in EU from adverse drug reactions (ADRs) [EC 2008]
- 2012 new EU pharmacovigilance system launched:
  - Planned surveillance; robust assessment; binding action; transparency and engagement

Drug Saf (2017) 40:855–869
DOI 10.1007/s40264-017-0572-8

LEADING ARTICLE

Promoting and Protecting Public Health: How the European Union Pharmacovigilance System Works

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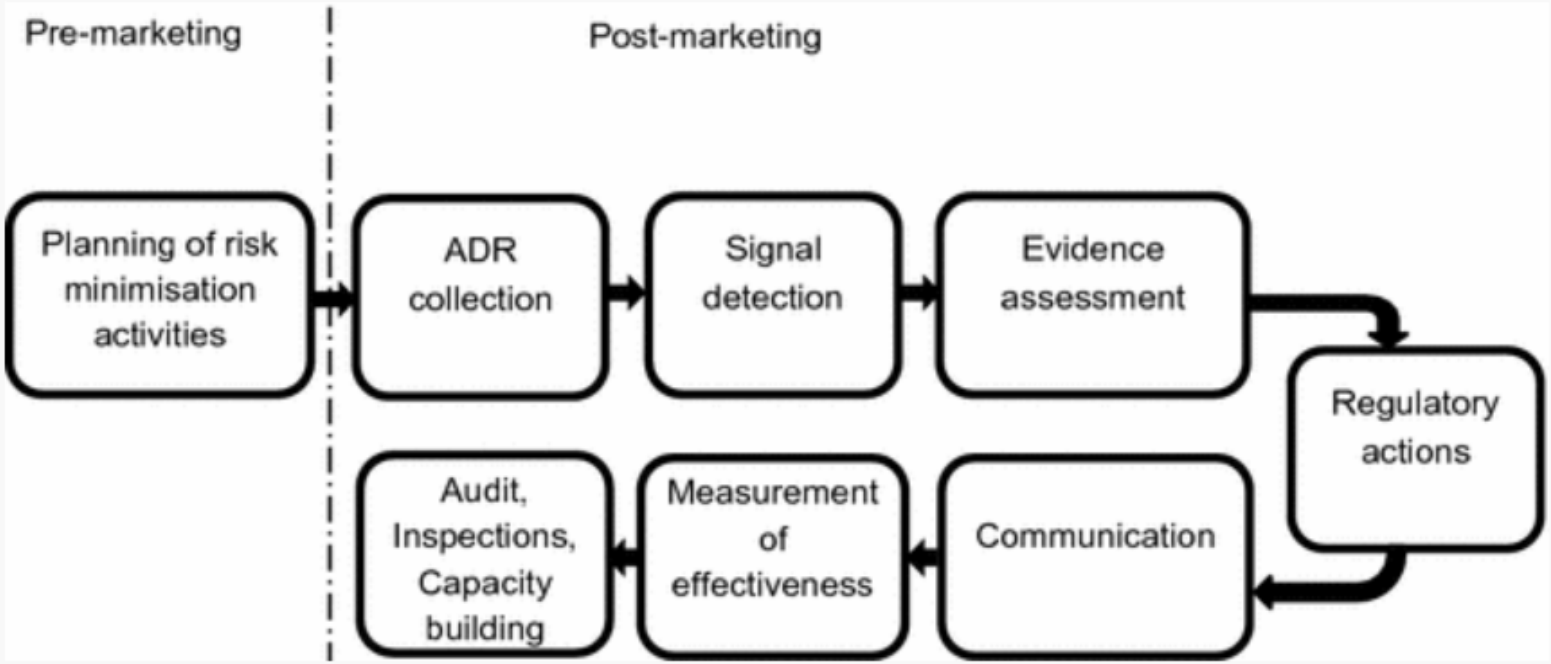


EudraVigilance – Processing of reports of suspected adverse reactions

Number of individual case safety reports (ICSRs) processed: 2018

- 2,015,881 reports of suspected adverse reactions to EudraVigilance (37% increase compared to 2017).
- 1,028,386 of these reports originated from the EEA (89% increase compared to 2017).
- The number of reports submitted directly by European patients and consumers through the national competent authorities (NCAs) and marketing authorisation holders (MAHs) (172,762).

Increases mainly due to non-serious EU reports being included in the EudraVigilance database

EudraVigilance –as data hub

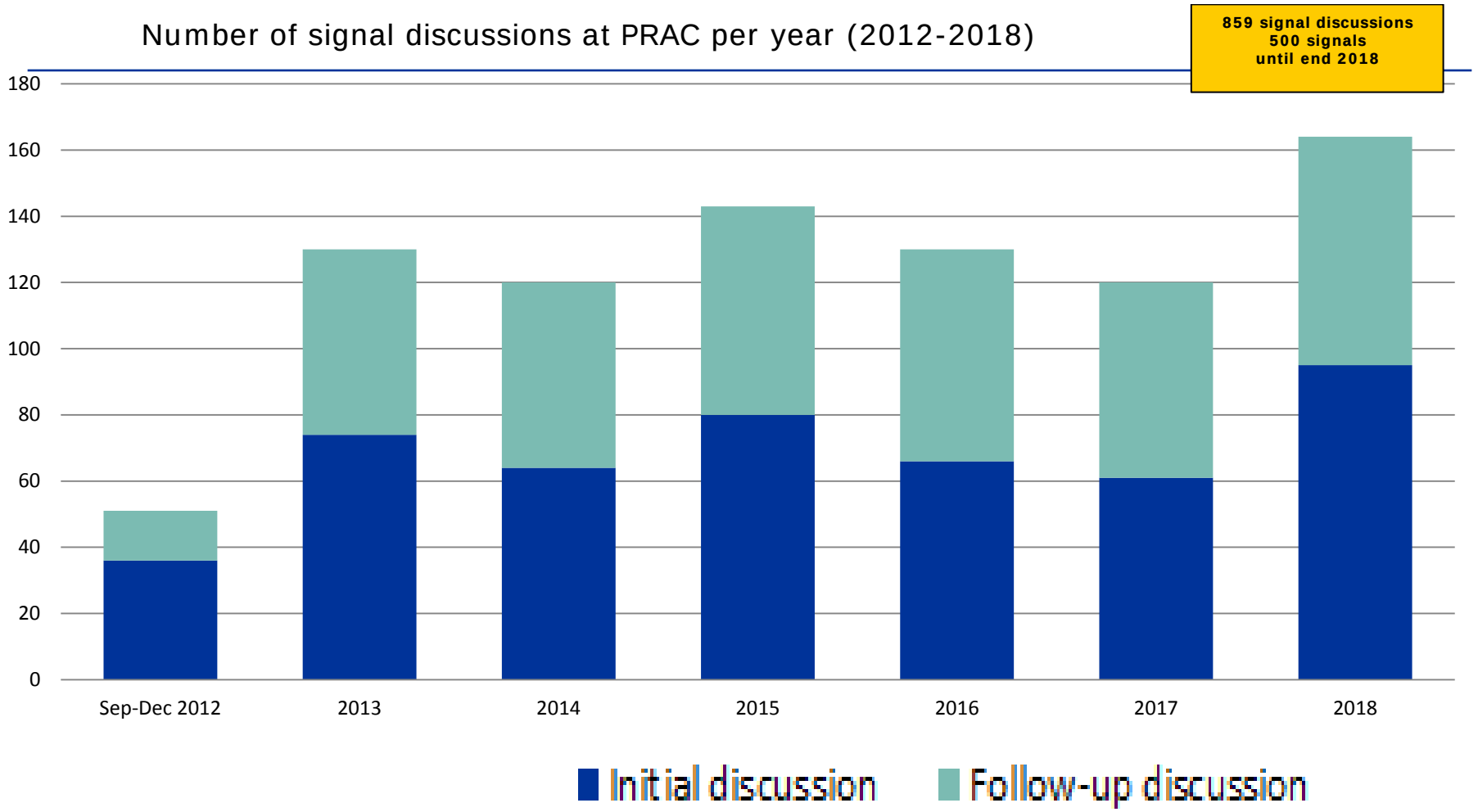
2018:

- 344,962 ICSRs were rerouted to NCAs following receipt of the reports from MAHs
- 1,010,544 ICSRs were forwarded to WHO.
- 14,247,526 ICSRs downloaded by companies .

Patient Reporting

Trend of ADR reports from patients and consumers received in the EEA by NCAs and MAHs and reported to EudraVigilance.

Safety signals: faster detection and management of new and changing safety issues

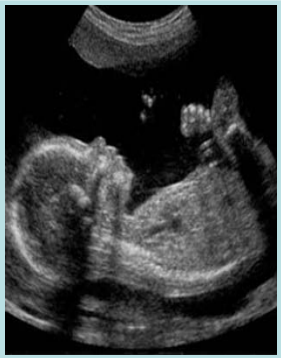


PCWP – HCPWP work plan

- "Understanding how severity of ADRs is analysed in relation to benefit-risk assessment"
- "Discuss how to increase awareness amongst patient and consumer organisations about ADR reporting and Eudravigilance data"

<u>Proposal</u>

- 2020 Study on the impact of non-serious reports on signal detection
- 2021 Study features and how to best use patient reported ADRs



Sildenafil (REVATIO, VIAGRA)

- Pulmonary hypertension & death in infants exposed in utero
- Clinical trial in growth retardation (off label)

27/07/2018 - EMA notified that trial suspended
05/09/2018 – PRAC agrees letter warning to professionals

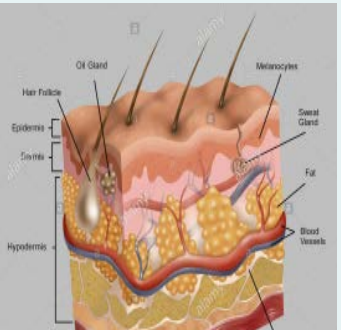
Rivaroxaban (XARELTO)

- Increased mortality, bleeding and clots in patients treated for trans-catheter aortic valve replacement (off label)

13/08/2018 - EMA notified that trial suspended
14/08/2018 – EU Incident Management Network teleconference
05/09/2018 – PRAC agrees letter warning to professionals

Hydrochlorothiazide

- Risk of lip and non-melanoma skin cancer

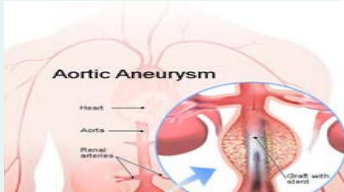


12/2017 - Two Danish epidemiological studies published
Q1 2018 EMA epidemiological study
05/09/2018 – PRAC agrees letter warning to professionals

Fluoroquinolones

Risk of aortic aneurysm and dissection

2015-2018 - Epidemiological and non-clinical studies
05/09/2018 – PRAC agrees letter warning to professionals



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Identifying opportunities for 'big data' in medicines development and regulatory science

Report from a workshop held by EMA on 14–15 November 2016

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DOI: 10.1002/pds.4381

COMMENTARY

WILEY

Strengthening standards, transparency, and collaboration to support medicine evaluation: Ten years of the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP)

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1 | BACKGROUND

The European Medicines Agency (EMA) has the responsibility for the scientific evaluation, supervision, and safety monitoring of medicines in the European Union (EU) to ensure that their benefits outweigh their risks. While the roots of medicines' safety monitoring lie in the development of mechanisms for spontaneous reporting of suspected adverse reactions by health-care professionals and patients, the importance of using the full spectrum of evidence including observational studies has long been acknowledged.[1-3] The risk management system introduced in the EU in 2006 highlighted the need to build capacity and to facilitate the conduct of multicenter independent postauthorization studies to investigate important risks or missing committees, and the European Commission.[5] The European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP; www.encepp.eu) was launched on June 28, 2007 with 79 participants who agreed to develop an active research network based on principles of transparency, scientific independence, and common quality standards. The European Network of Centres for Pharmacoepidemiology and Pharmacovigilance was presented in a symposium at the 24th International Conference on Pharmacoepidemiology and Therapeutic Risk Management in August 2008.[6] Ten years on, we review ENCePP's main achievements, discuss its impact on the benefit-risk evaluation of medicinal products in Europe, and outline future perspectives.

Landscaping of datasources and initiatives in EU

EUROPEAN MEDICINES AGENCY

Characterisation of EHR databases in Europe

BMJ Open

Electronic healthcare databases in Europe: descriptive analysis of characteristics and potential for use in medicines regulation

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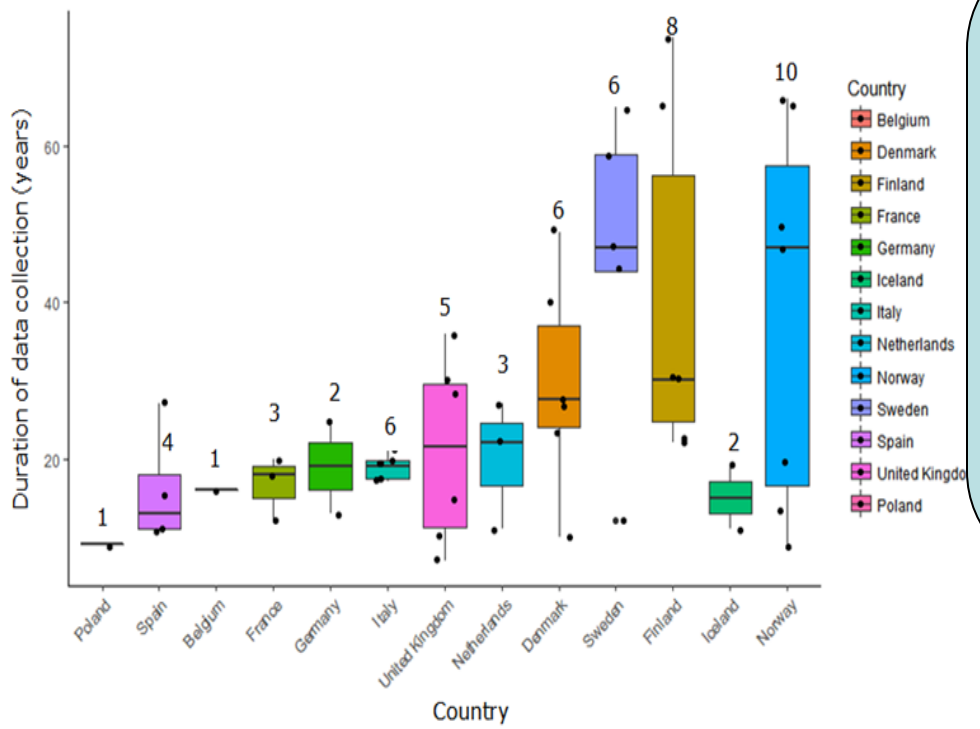

30%-50% of all PASS use EHDs as their main data source

Use of EHDs in pre-authorisation research is currently limited (understanding the natural history of diseases, historical control data)

Only 13 member states have electronic health databases suitable for regulatory decision making

High heterogeneity in data collected or available through linkages and in data quality

PCWP – HCPWP work plan

- "Responding to requests where real world evidence gaps have been identified in relation to a safety concern under investigation and on the possible RMM"

Proposal

- Development of guidance on 2ndary use of health data (may include data protection)
- Support discussions on how to access and analyse EHRs to strengthen product monitoring

Conclusions

- We built the new EU pharmacovigilance system for better health protection and promotion
- Collaboration can make the system even better