EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Report on pharmacovigilance tasks of the EU Member States and EMA, 2019-2022

PCWP/HCPWP joint meeting
28 June 2023

Presented by Aniello Santoro

Background

Article 108b of Directive 2001/83/EC: the European Commission (EC) should make public a report on the performance of PV tasks by Member States (MSs) in 2015 and thereafter every 3 years

Regulation 726/2004, Article 29:
The Commission shall make public a report on the performance of PV tasks by the Agency on 2 January 2014 at the latest and subsequently every 3 years thereafter.

EUROPEAN COMMISSION

Brussels, 8.8.2016
SWD(2016) 284 final

COMMISSION STAFF WORKING DOCUMENT
Accompanying the document

Commission Report

Pharmacovigilance related activities of Member States and the European Medicines Agency concerning medicinal products for human use (2012 – 2014)

{COM(2016) 498 final}

HMA
Heads of Medicines Agencies

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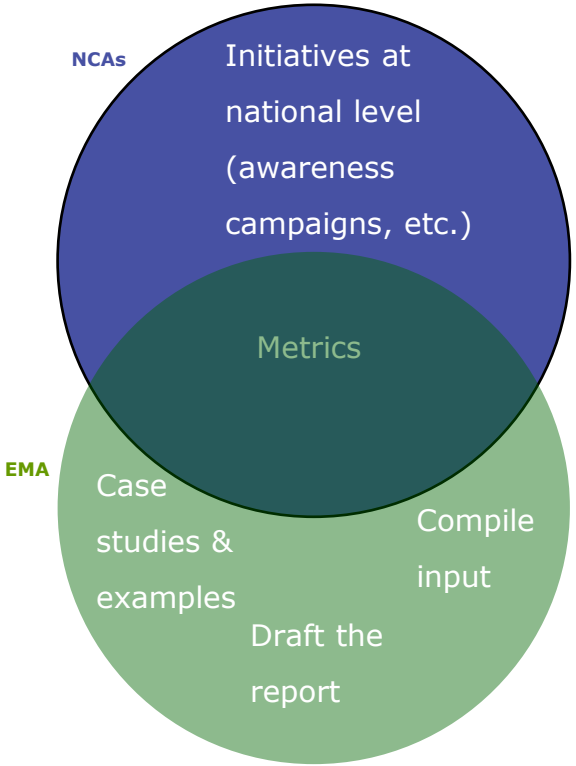
10 December 2019

Report on pharmacovigilance tasks from EU Member States and the European Medicines Agency (EMA), 2015-2018

https://www.ema.europa.eu/en/news/report-how-eu-ensured-safety-medicines-during-covid-19

Roles and responsibilities



Data on national PV activities collected from all MSs

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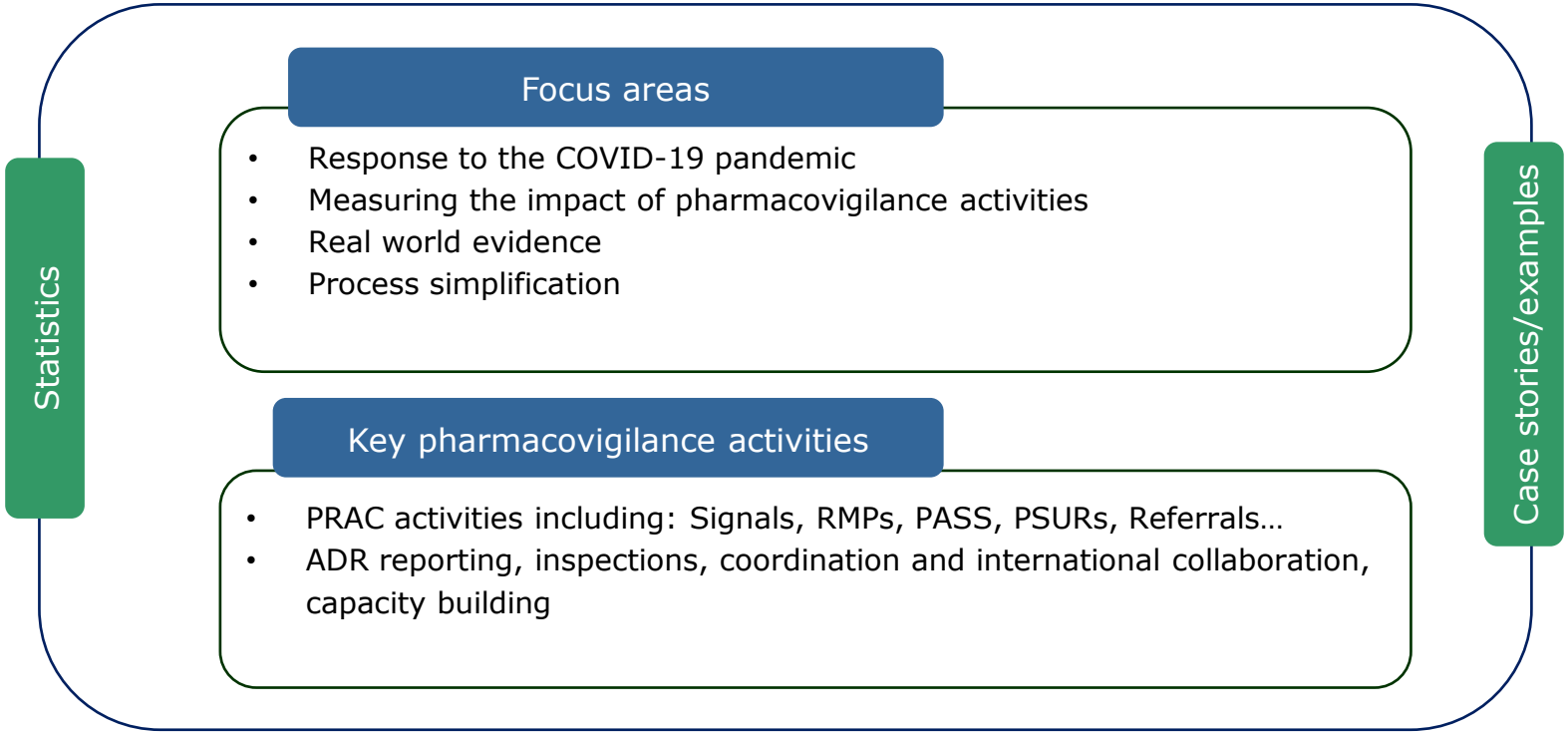
Data on EU PV activities collected internally

High level overview of report



Effective EU response to the pandemic

- **Timely** reporting of ADRs to EudraVigilance

~2M EEA ICSRs for COVID-19 vaccines

- **Intensified monitoring** and application of methods to harness unprecedented volume of data

Near real time monitoring of AESIs, dashboards, O/E analyses, 56 SSRs

- Funding of **independent studies** to prepare for monitoring and better characterise risks

11 studies contracted out to consortia, 6 of them finalised

- Enhanced **international collaboration** to share information and align research questions and methods

Ad-hoc confidentiality agreements, non-EU regulators attended Committee meetings as observers

- Proactive **communication**, enhanced **transparency** and **engagement** to address public demand

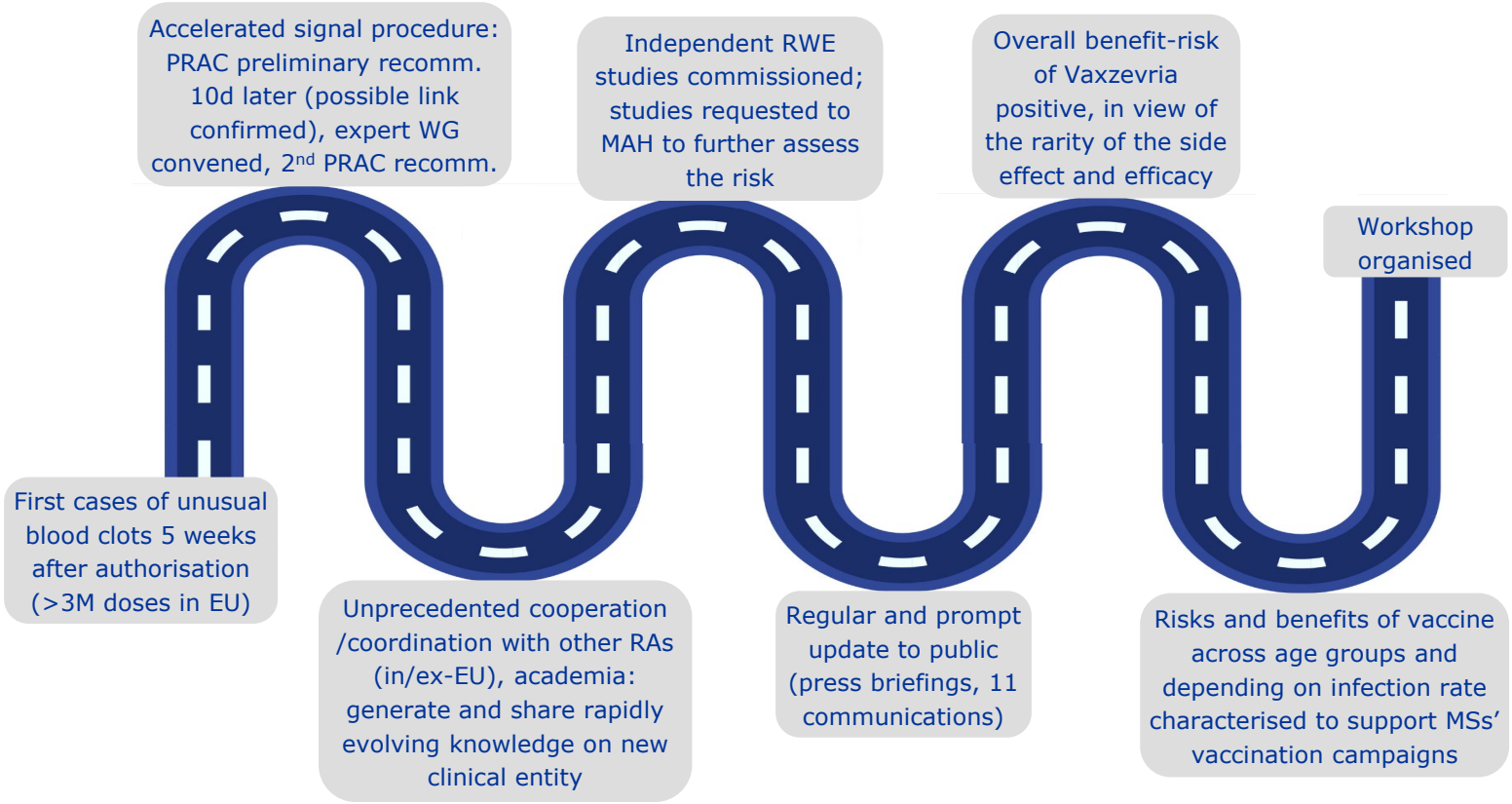
Full RMPs for vaccines/therapeutics and >50 safety updates for vaccines published, >30 press briefings, 4 public stakeholders meetings, Info cards, health advice

- **Flexibility, dedication** and **commitment** of EU Network and all stakeholders

Ad hoc Committee meetings, 1 extraordinary MedDRA update, prioritisation & acceleration of procedures

Data until December 2022

TTS and Vaxzevria: how the EU PV system worked



Other key messages

- Framework for measuring the impact of PV activities strengthened: systematic **follow-up** on outcomes and evaluation of need for further action; greater stakeholders' **engagement** to help improve RMMs implementation

PRISMA pilot

- **DARWIN EU®** established: it allows access to large healthcare databases across the EU and supports greater use of RWE in decision making

10 data partners & 4 studies initiated in 2022, >100 studies/year by 2025

- Processes have been **simplified** or automated to gain efficiency

Hybrid (remote/on-site) PV inspections, PV inspections migrated to IRIS

Abbreviations

ADR	Adverse drug reaction
AESI	Adverse event of special interest
DARWIN EU®	Data Analysis and Real-World Interrogation Network
EU	European Union
EEA	European Economic Area
ICSR	Individual case safety report
M	Million
MAH	Marketing authorisation holder
MedDRA	Medical dictionary for regulatory activities
MS	Member State
O/E	Observed versus expected analysis
PASS	Post-authorisation safety study
PRISMA	PRAC Risk Minimisation Alliance
PSUR	Periodic safety update report
PV	Pharmacovigilance
RA	Regulatory Authority
RMM	Risk minimisation measure
RMP	Risk management plan
RWE	Real world evidence
SSR	Summary safety report
WG	Working Group

Thank you

Any questions?

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