EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

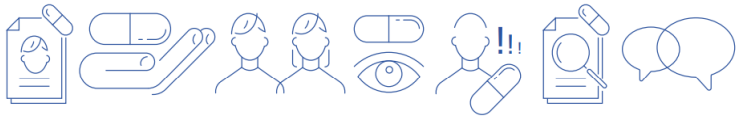
Periodic safety update report (PSUR): Adherence to PRAC recommendations for national authorized products (NAPs)

Reflexion on the PSUSA NAP procedure – promoting and protecting Public Health in the EU

16th Industry Stakeholder Platform – Operation of EU Pharmacovigilance

Presented by: Viola Macolic Sarinic (EMA) on 17 November 2021

Background



The EU pharmacovigilance system is build to ensure the promotion and protection of public health through a proactive, transparent, risk proportionate and patient-centred approach

The PRAC is at the core of the operations of the EU pharmacovigilance system and is responsible for assessing and monitoring the safety of medicines in the EU

NAP PSUSA procedures also assessed and monitored by PRAC – experience of one decade of the introduction of the 2010 Pharmacovigilance legislation in the EU

NAP PSUSA procedures and adherence to PRAC recommendations – reaching the patients in all Member states and its public health impact in the EU

Outcomes, benefits and short comes of the procedure, its effect on recourses and possible simplification of processes as future drivers of the system

EU – European Union; PRAC – Pharmacovigilance Risk Assessment Committee; PSUSA - PSUR single assessment procedure; NAP – national authorized product

The Pharmacovigilance System in the EU

Promote

- Fulfil unmet medical needs
- Plan evidence generation through lifecycle
- Plan for optimal risk management at authorisation
- Robust PV systems support authorisation decision

Protect

- Robust monitoring for new safety issues
- Rapid decision making
- Effective action to minimise risk
- Demonstrating positive impact

From: Santoro A, Genov G, Spooner A, Raine J, Arlett P. Promoting and Protecting Public Health: How the European Union Pharmacovigilance System Works [Internet]. 2017; Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5606958/

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PSUSA Statistics

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PSURs and PSUSAs finalised	2016	2017	2018	2019	2020
PSURs stand-alone (CAPs only) finalised	511	540	537	558	516
PSURs single assessment finalised	280	302	364	270	258
PSURs single assessment (CAPs with NAPs) finalised	16	39	43	48	49
PSURs single assessment (NAPs only) finalised	264	263	321	222	209
Total outcomes	**791**	**842**	**901**	**828**	**774**

PRAC outcomes of PSURs and PSUSAs	2016	2017	2018	2019	2020
Maintenance	**637**	**680**	**735**	**655**	**630**
NAPs only		207	245	166	161
CAPs/NAPs and CAPs only		473	490	489	469
CHMP Variation	**154**	**162**	**166**	**173**	**144**
NAPs only		56	76	56	48
CAPs/NAPs and CAPs only		106	90	117	96
Total outcomes	**791**	**842**	**901**	**828**	**774**

Source: https://www.ema.europa.eu/en/documents/annual-report/2020-annual-report-european-medicines-agency_en.pdf

Periodic Safety Update Reports

A legal requirement on MAHs to provide an evaluation of the benefit-risk balance of their medicines at intervals as evidence accrues in clinical use.

A PSUR is a comprehensive, concise and critical analysis of the benefit-risk balance of a medicinal product in clinical practice, including its use in unauthorised indications as well as in line with the product information.

PSUR reporting cycle is linked to the risk management system of a medicinal product.

EURD list.

The outputs of the assessment of PSURs are legally binding on the MAHs.

The PRAC performs a single joint assessment of all related PSURs (PSUSA), regardless of the authorisation procedure and the EU country of authorisation of individual products. This translates into a strengthened benefit-risk review of medicines across the EEA, and hence into enhanced safety monitoring and rapid labelling changes across the EU.

Periodic Safety Update Reports

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PSUR timeline

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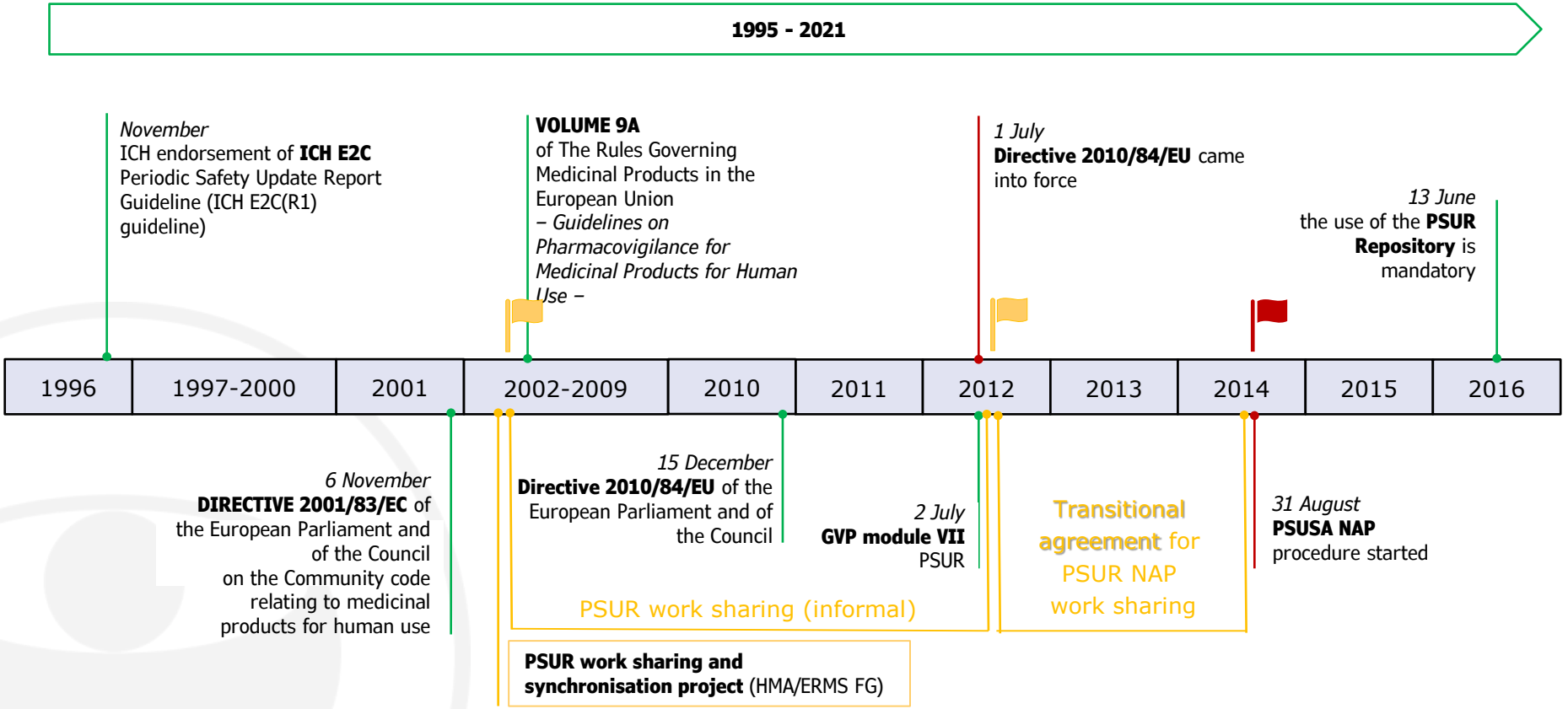

Proposed project objectives on the adherence to PRAC recommendations for NAPs

- Understand the **extent and the time frame** in which the **recommendations of the PRAC** (for the variation of the PI) are implemented at national regulatory level in EU Member States.
- **Type of proposals** provided by the PRAC (for the variation of the PI) for the NAPs based on the periodic benefit/risk-review, as part of the PSUSA procedure.
- To find out whether there is a **link between the PSUR cycle** of active substances **and the outcome of the procedure** and **the type of proposals** that are provided (for the variation of the PI) for the NAPs during the EU single assessment procedure.

Questions to MAHs:

1. Reflection on NAP PSUSA cycles and PSUSA outcomes

2. Implementation of PRAC recommendations for NAP PSUSAs on the level of the member states – MAH experience – improvements and obstacles

3. Time to implementation – final PI update/implementation of EM available for the HCPs and patients

4. Optimisation of the PSUSA process and implementation of PRAC recommendation – interaction with PRAC

5. Impact on Public health of the PSUSA procedure from the MAHs point of view (10 years of experience in NAP PSUSA procedure)

Thank you for your attention

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