EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Update on the PSUR and PSUSA roadmap

7th industry stakeholder platform - operation of EU pharmacovigilance legislation

Presented by Ana Zanoletty on 4th April 2016
Procedure Management Department

Agenda

- Introduction
- PSUR Roadmap and issues it will address
- Agreed principles and implementation timeline
- Questions and discussion

Introduction

New Pharmacovigilance legislation

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changes in PSUR submission requirements and content; strengthened coordination

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Increased experience
Increased challenges

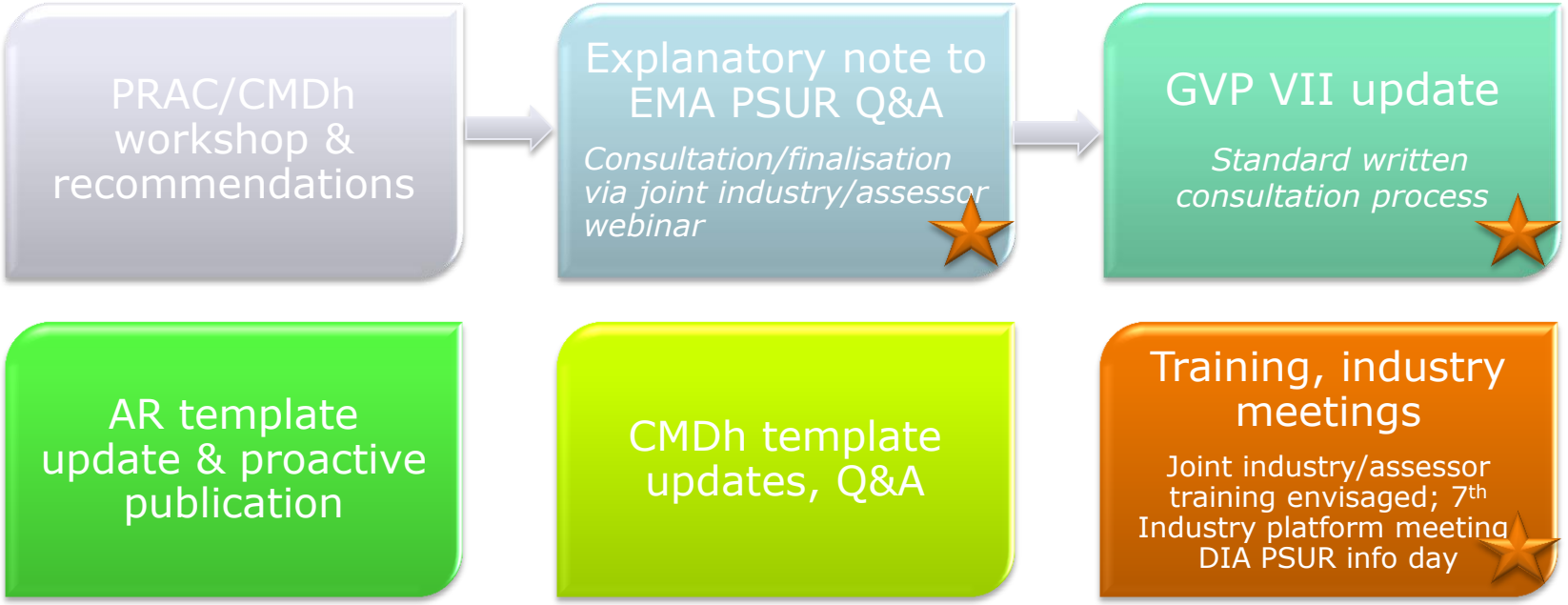
Concept of the PSUR, its assessment and role in the lifecycle of a medicinal product (critical appraisal)

Evidentiary standards in submissions and outcomes

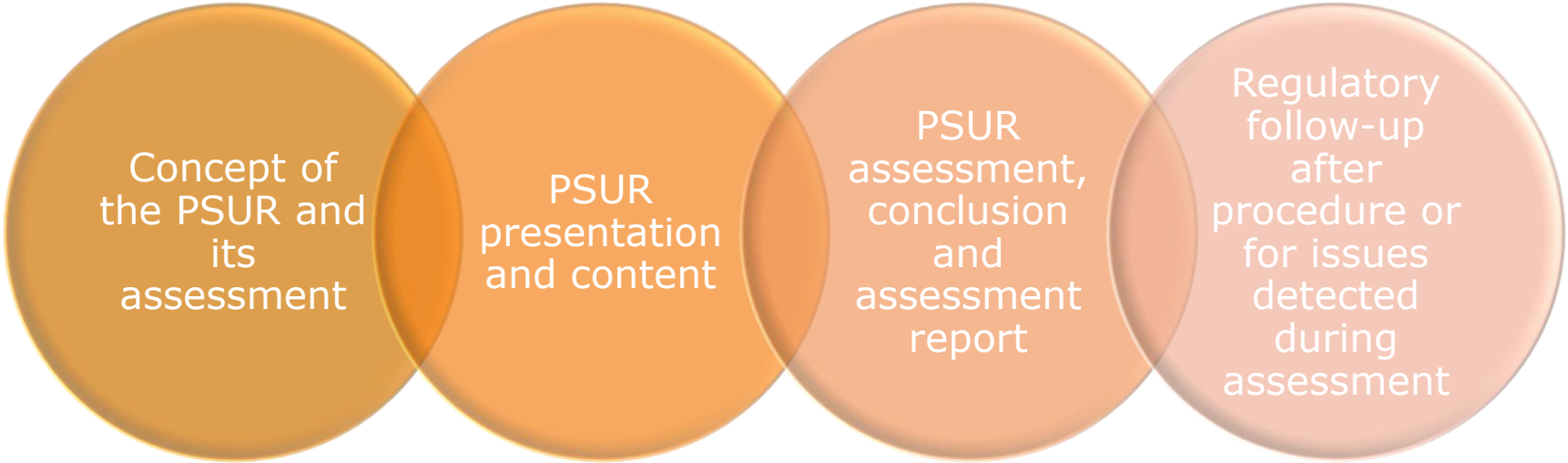
Regulatory follow-up after procedure or for issues detected during assessment

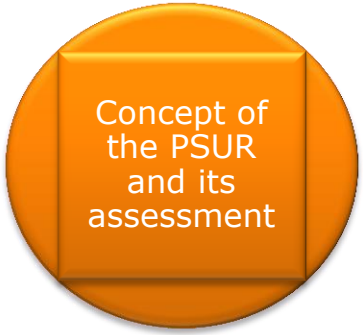
PSUR Roadmap

PSUR Roadmap elements



Honing in on the issues – PRAC/CMDh workshop (Jan 2016)





- What should drive for the assessment of a PSUR (single) assessment?
- Can a PSUR procedure add a new indication to approved medicinal products?
- Reaching a common position on the B/R when different indications may be authorised in different MS and the level of information included in the SmPC may be very different as well?
- Strength and nature of the evidence needed to support regulatory action? Does this differ depending on the stage in a medicinal product's lifecycle?

- Lack of experience/knowledge in the submission of data some PSURs: e.g. safety specifications are all the adverse events listed in section 4.8; information is not placed in the correct sections; no critical analysis of the data…): What is the level of evidence/information that should be provided, especially in the particular context of the EU single assessment in each of these sections?
- Setting the Reference Safety Information in the context of the product information in EU

- Handling of refuted signals and further follow up
- Handling of close monitoring and what is expected of the MAH
- Can/should the PSUSAs be used as a tool for harmonisation of the SmPC/PL?
- Can/should the PSUSAs be used as a tool for harmonisation of the safety specifications?
- Implementation of outcomes from other procedures?
- Conclusions on combination PSUSAs vs mono substances and vice versa?

- What is the regulatory/procedural position in cases where during the PSUSA assessment non-compliance with previous EU positions (e.g. PV referral) are detected?
- What to do when an issue cannot be finalised within the PSUSA?
- Implementation of PSUSA outcomes at national level?

Starting point - key principles (Industry focus)

- Reliance on the data (interval & cumulative) provided in PSUR → importance of data quality → prerequisite for adequate assessment
- The PSUSA is not a tool for harmonisation of product information. Consider using other procedures to reach harmonisation
- Update of safety specifications only if important new risks. Safety evaluation needs to be in context of the reference safety information (RSI) and not based on each national SmPC for a product and the RSI needs to be set into EU context.
- Improve communication on timeframe for implementation of NAPs outcomes

Starting point - key principles (Assessor focus)

- Critical appraisal should be undertaken considering the maturity of the product and its place in therapeutics
- Preparation is key, potentially reducing need for follow up; early discussion at PRAC where helpful
- New section for "Other considerations" in PRAC AR to flag important issues
- Follow up requests should be exceptional and scientifically justified (process under discussion at CMDh)
- EURD List updates should involve GPAG

Implementation timeline

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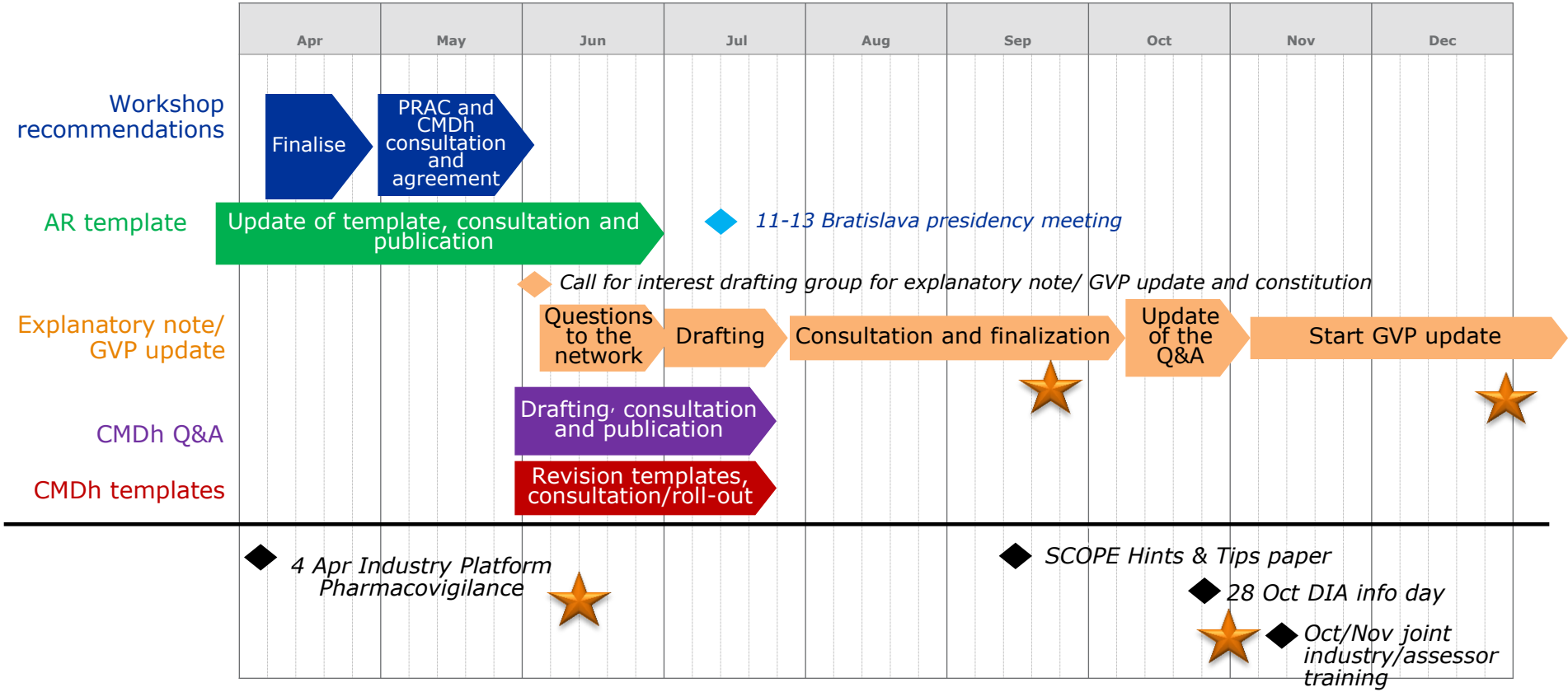

Questions and discussion

Thank you for your attention

Further information

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