EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

New Pharmacovigilance Legislation

Q&A on practical transitional measures

5th Stakeholders forum– 25 May 2012

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Q&A document - principles

- Joint EMA / MS document
- Covers CAPs and NAPs (including MRP and DCP)
- Practical aspects to complement Commission Q&A
- Living document

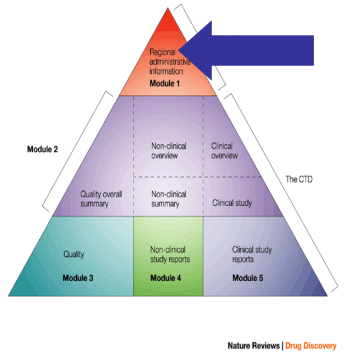
Q&A document - Content

- Themes covered:
  - GVP
  - PSMF
  - RMP
  - PASS
  - PSUR
  - Literature monitoring
  - PI and black symbol
  - ADR and Signal Management
  - Renewals

GVP and Volume 9A applicability

- Vol 9A will be superseded by the GVP
- Vol 9A remains applicable, until the end of the transition period or until the final GVP modules are published.

Summary of Pharmacovigilance System



1.8.1 DDPS / **NO** DDPS

Detailed description of the pharmacovigilance system in the MAA

OLD

(1.8.1) Summary of pharmacovigilance system

— **proof** at his **disposal a qualified person** responsible for pharmacovigilance,
— the **Member States in which the qualified person resides and carries** out his/her tasks,
— the **contact details of the qualified person**,
— a statement **necessary means to fulfil the tasks and responsibilities listed in Title IX,**
— **a location of the pharmacovigilance system master file**

Can be one **single** statement signed by the applicant/MAH and the QPPV

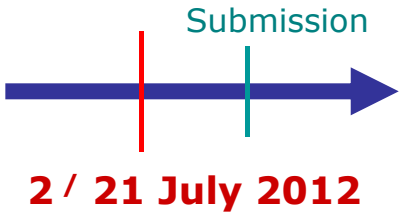
PSMF is not part of the MA

to be provided within 7 days to authorities upon request

NEW

When to introduce the PhV system summary?

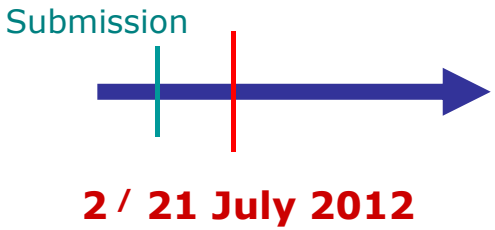
For new MAAs and renewal application :



From 2 / 21 July 2012:

New MAAs and renewal applications (including 1-yr renewal for conditional MA) submitted from 2 / 21 July 2012 shall include a summary of the PhV system.

For ongoing MAAs and renewals :



Before 2 / 21 July 2012:

MAAs applications submitted before 2 / 21 July 2012 shall include a DDPS.

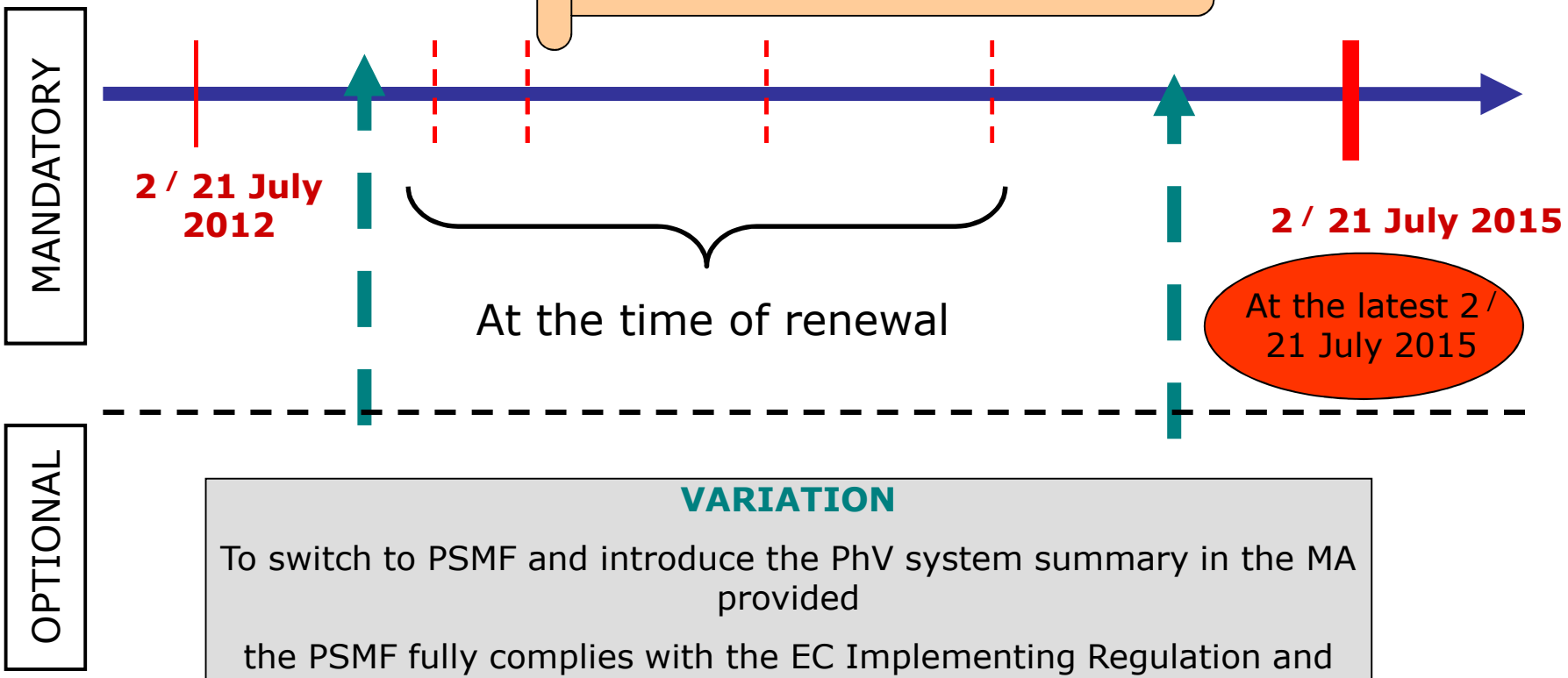
Applicants are not required to upgrade their applications to the summary of PhV system during evaluation, nor for pending renewals.

The same transition for the switch to PSMF will apply as for existing MAs.

Early introduction of the PhV system summary

For existing MAs:

The obligation to maintain a PSMF and introduce a **PhV system summary** apply **to all MAs** with or **without** a DDPS



VARIATION

To switch to PSMF and introduce the PhV system summary in the MA provided

the PSMF fully complies with the EC Implementing Regulation and details in the GVP

Variation for the PhV system summary

New proposed type IA_{IN} variation

For introduction (MA with/without DDPS)

or change (in QPPV name or contact details or PSMF location)

to a summary of pharmacovigilance system.

- Updating of variation classification guideline ongoing.

- In the absence of a specific variation, an article 5 (recommendation on unforeseen variations) of the variation Regulation is expected to be triggered by a Member State.

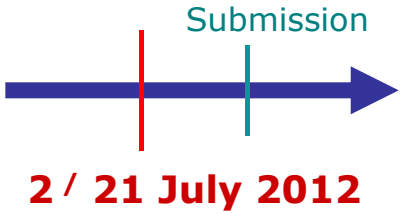
Should follow the rules for grouping of type IA_{IN}

CAP : 1 type IA_{IN} affecting several products of the same MAH can be grouped

NAP : please refer to the arrangements provided in the CMDh Best Practice Guides on variations

When to introduce RMP?

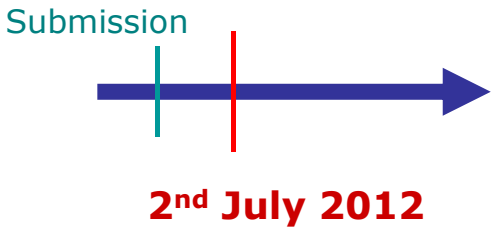
For new MAAs application :



From 2 / 21 July 2012:

New MAAs including generics submitted from 2 / 21 July 2012 shall include a RMP.

For ongoing MAAs :

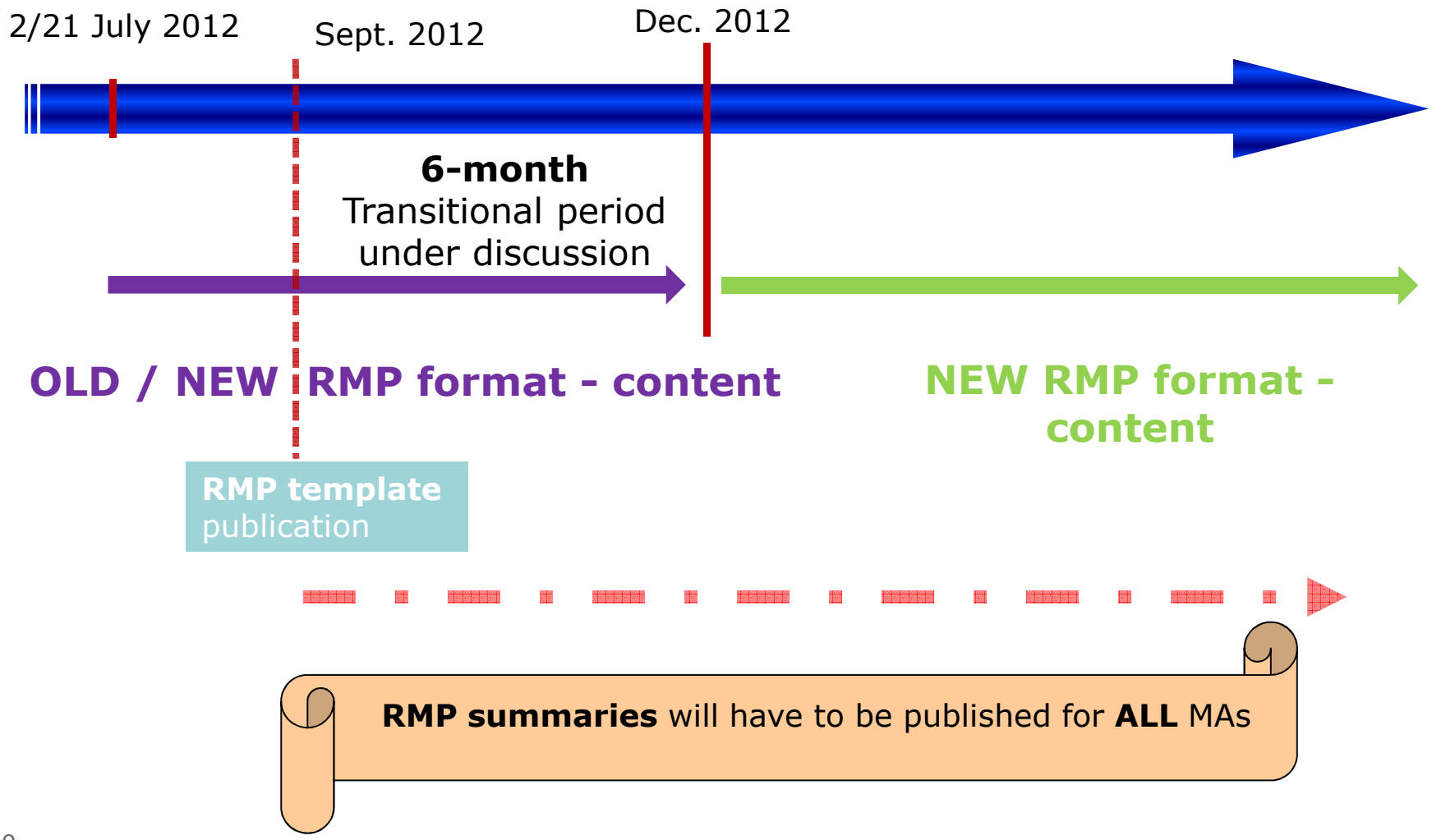


Before 2 / 21 July 2012:

MAAs submitted before 2 / 21 July 2012 shall include a RMP, if applicable.

Applicants are not required to upgrade their applications to include a new RMP during evaluation, unless requested by the Competent Authority.

Which format/content for the RMP?

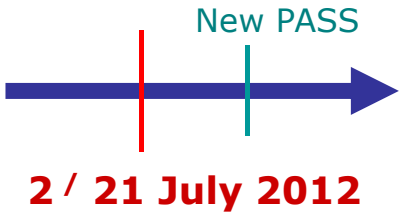


Herbals / Homeopathics

	Traditional Herbals simplified registration	Homeopathics simplified registration
PhV system and PSMF	**APPLIES**	DOES **NOT** APPLY
Submission of PhV system summary	DOES **NOT** APPLY	DOES **NOT** APPLY
RMP	DOES **NOT** APPLY	DOES **NOT** APPLY

For herbal and homeopathics other than those registered through the simplified procedures (resp. Art 16a and 14 of DIR)
→ the **new requirements above apply**

PASS - Principles



New PASS **imposed** to existing and new MAs as of 2/21 July as a condition to MA

RMP + Annex II for CAPs / National decision for NAPs

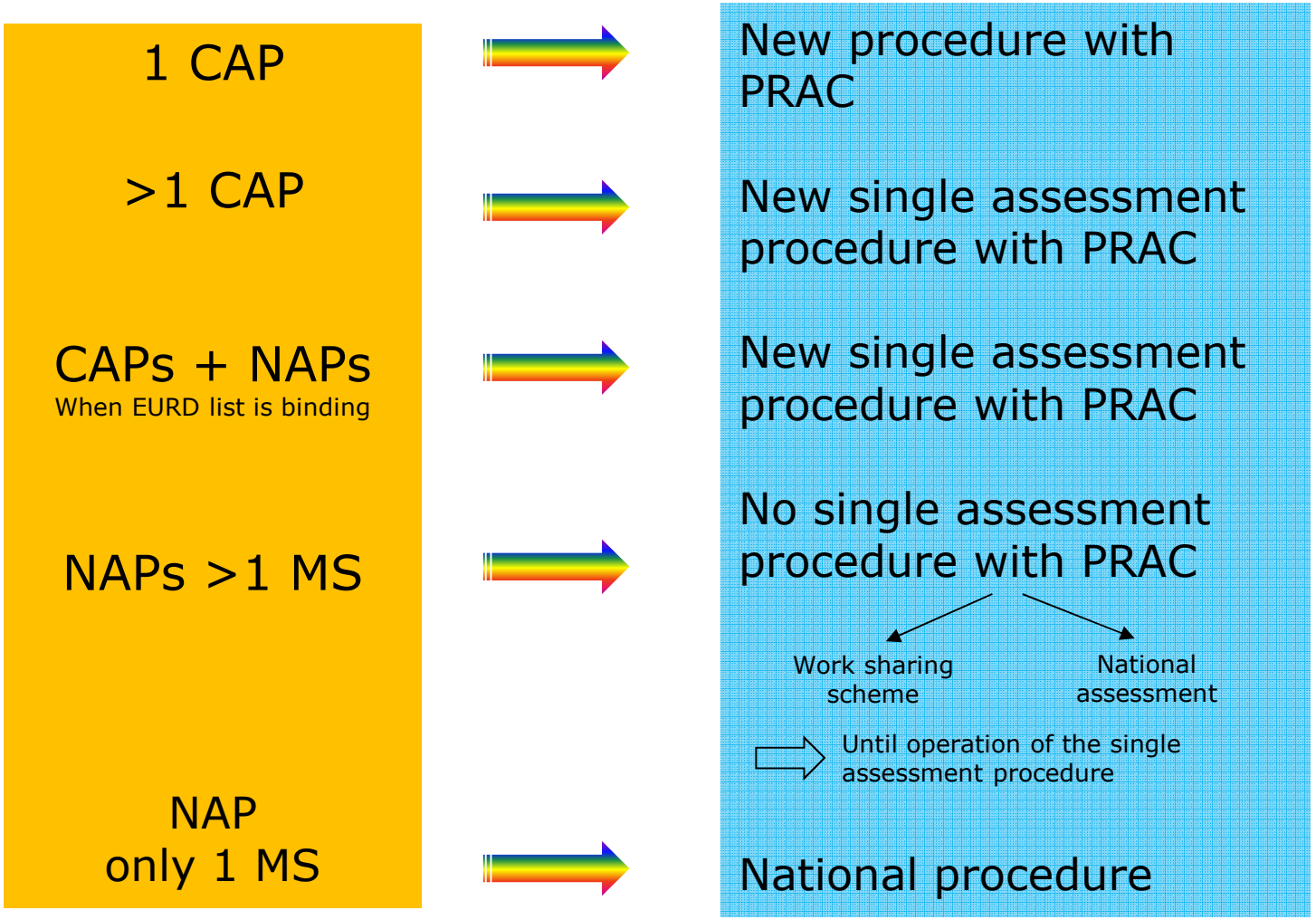
For joint studies, key elements or core protocol may become a condition to the MA

Will follow the new procedures (i.e. protocol + final study results) involving the PRAC

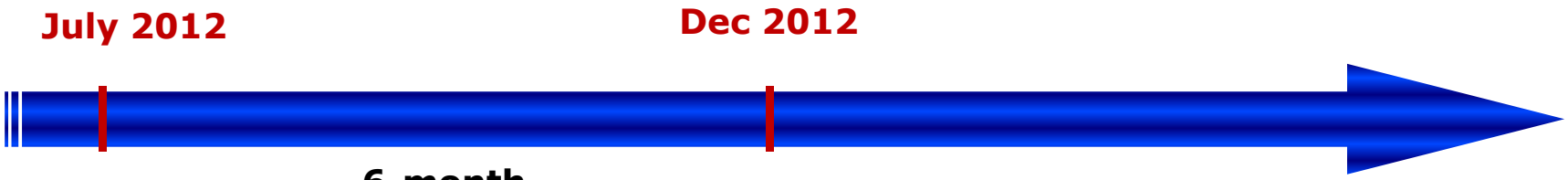
ENCEPP registration of PASS studies to meet transparency requirements

PSUR – Which procedure?

As of July 2012



Which format/content for the PSUR?



6-month Transitional period under discussion

NEW PSUR format - content

Old	New
Line listing	No line listing
B/R evaluation	B/R evaluation
Addendum	*Integrated*

Submission **70/90 days** after DLP

CAP: eCTD
NAP: updated table compiling Member States requirements

PSUR requirement derogation

NO obligation of submission of routine PSUR **unless**:

a) Condition in the MA

b) Request from authorities
i) lack of PSUR
or
ii) safety concerns

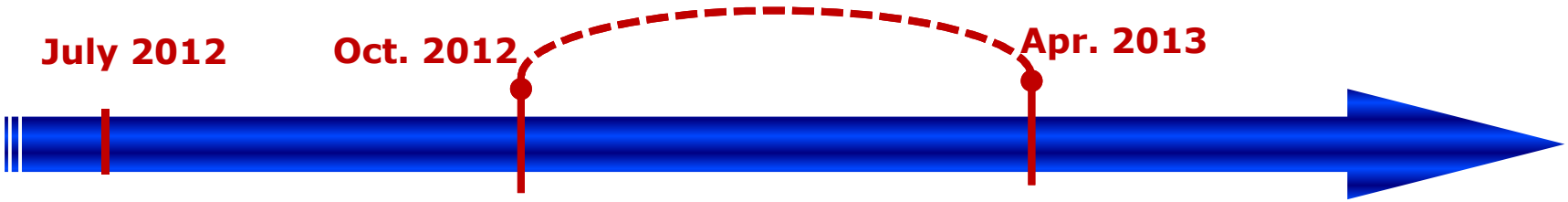
EURD list publication

- **Generics** – Art 10(1)
including where a statement to follow PSUR cycle of Ref. medicinal product
- **Traditional herbals** - Art 16a
- **Homeopathics** – Art 14
(simplified registration)
- **Well established use** – Art 10a

If not authorised under these legal basis

PSUR submission applies

EURD list



EURD list publication

EURD list **entering into force**

- Generics with statement that PSUR cycle **according to Ref. medicinal product** → NO longer a condition, **NOR an obligation to submit PSUR**
- Generics with statement that PSUR cycle **deviates from Ref. medicinal product** → continue to **submit PSUR** accordingly

Variation (?)
to align with EURD list

Product information and black symbol

Black symbol + **This medicinal product is subject to additional monitoring** + **Explanatory sentence**

Standard statement for reporting of ADR by patients and HCPs

- For **ALL** medicinal products (CP and national), the SmPC and PL shall include statements for HCPs and patients
- For medicinal products (CP and national) **subject to additional monitoring**, the SmPC and PL shall include black symbol

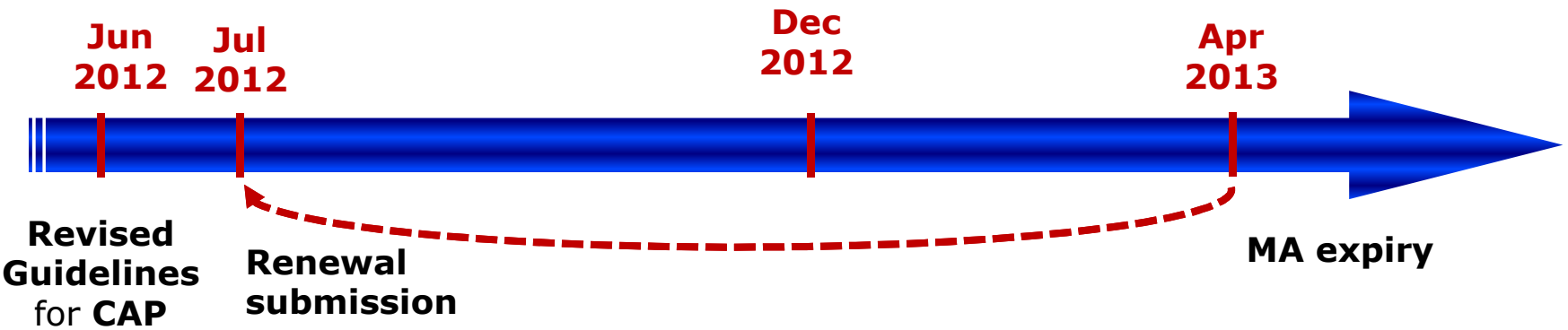
→ First black symbol to be **selected by the Commission** upon **PRAC recommendation**

→ Publication of the updated QRD templates with guidance for its implementation and introduction of black symbol (variation?)

ADR - What national reporting requirements?

Publication of a table compiling national requirements for reporting of non-EEA serious and EEA non-serious ICSRs

Renewal and new requirements



- No PSUR
- No PSUR addendum
- No line listing

Relevant information in the **clinical overview**

➡ to assess R/B balance of the medicinal product

As per renewal guideline

Conclusion

- Mailbox for enquiries QandA-PV-legislation@ema.europa.eu
  - No individual responses should be expected
  - Basis for an update of the Q&A
- Next update anticipated in July 2012

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Any questions?