European Federation of Pharmaceutical Industries and Associations

Compliance Check & Validation of Applications with an agreed PIP

EFPIA Info Day 24th February 2009

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Compliance Check Objectives

- Meet all objectives of the Paediatric Regulation

  (compliance check at MAA validation & compliance check for SPC purposes)
- Designed as easily manageable administrative procedures
- No delay of the submissions or validation of the marketing authorisation for adults or children
- Industry seeking pragmatism, predictability & transparency

Potential divergence & concerns

- Draft EMEA compliance check procedure published in July 2008 for consultation
  - no final version available
- Relation to Recital (16) of the Paediatric Regulation ?

  - *"The existing procedures for the marketing authorisation …should not be changed".*

  - From Recital (11) it follows that competent authorities should check compliance with the agreed PIP and any waivers and deferrals at the existing validation step for MAAs."
- As drafted, the procedure does not foresee any re-examination of the PDCO compliance opinion

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EFPIA Position on draft EMEA compliance check process

Submitted to EMEA 3rd November 2008

Compliance Check Principles & Criteria

- Specific, predictable and transparent criteria
  - Will guide Industry to execute the PIPs in a compliant fashion
  - Avoid need for late PIP modifications prior to MAA
  - Enable any member of PDCO, staff of EMEA or national regulatory authorities to verify this compliance objectively
- Streamlined and Certain outcomes
  - Avoid revocation of initially positive PDCO compliance opinion during the scientific evaluation by another Committee or Authority
- Resolution process for divergent positions required to ensure fair treatment of all stakeholders

Enabling Operational Efficiency

- The applicant can choose to request a compliance check by PDCO in advance of the procedure
- Agree that certain standard phrases are used in EMEA PIP Decisions
- Use Clinical Study Report synopsis to document compliance
  - concise summary of the full study including the results for all relevant elements of the PIP Decision
- Timely issuance PDCO compliance opinion and the statement certifying full compliance with an approved PIP
- Need for routine involvement of PDCO in compliance checks for MAA validation ?
  - stretching scientific resources to be used for PIP evaluation

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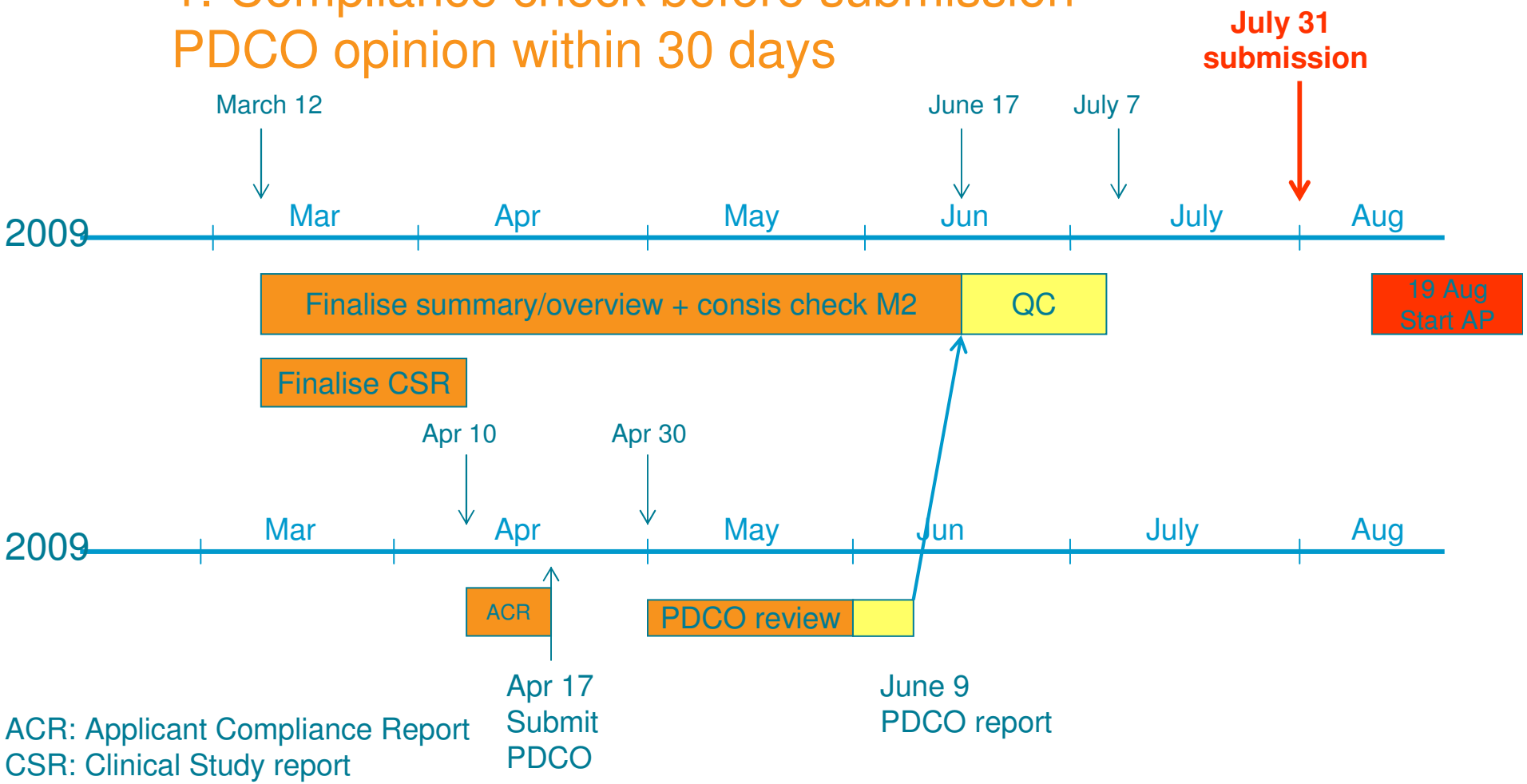
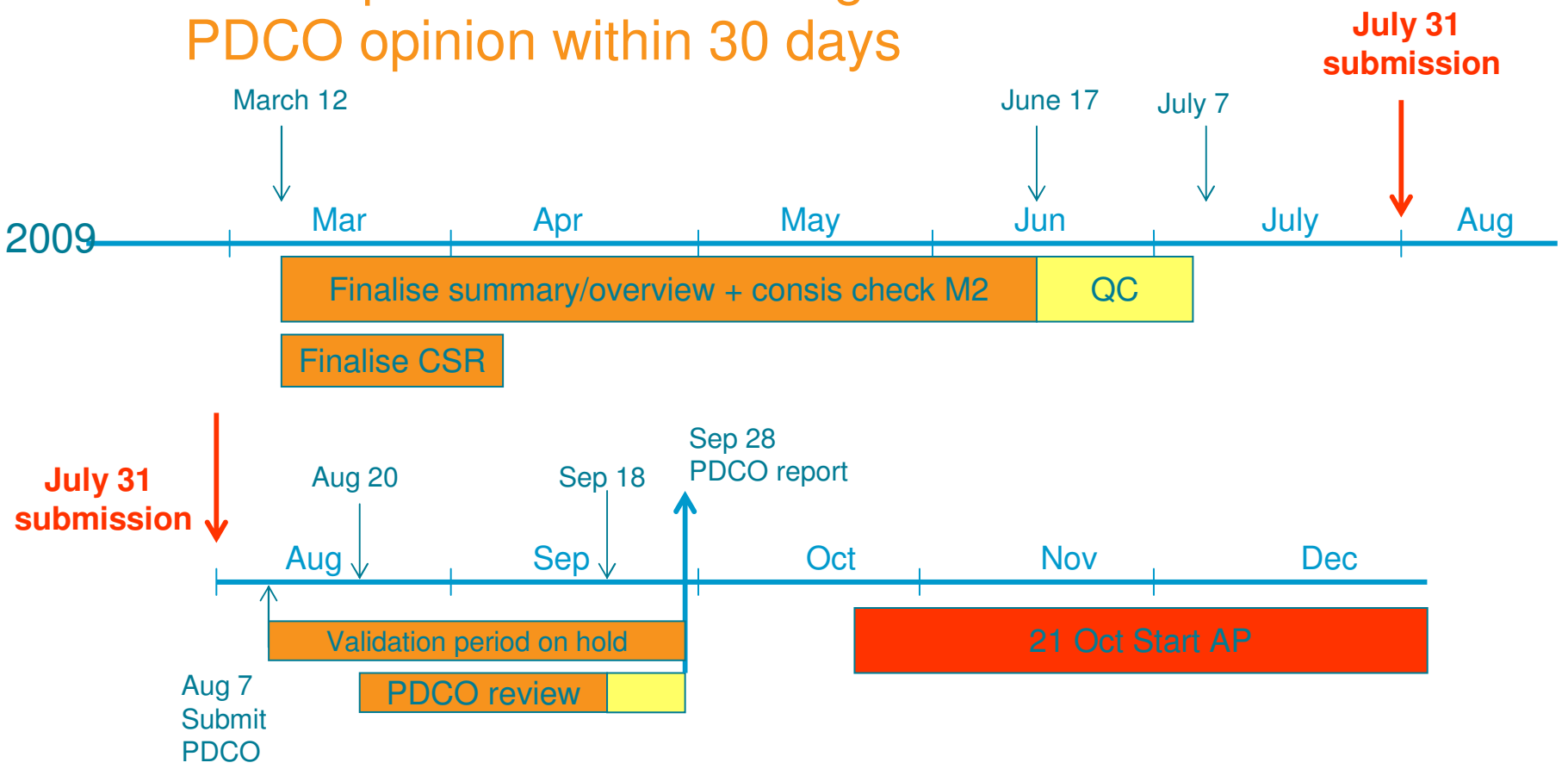
Case study: Impact on application submission timing

1. Compliance check before submission
PDCO opinion within 30 days



ACR: Applicant Compliance Report
CSR: Clinical Study report
M2: Module 2
QC: quality check
AP: approval process

2. Compliance check during validation
PDCO opinion within 30 days



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Current Impact Assessment (compliance check at time of MAA)

- "Required" from PDCO prior to MAA or Variation submission, if study data had been obtained
  - Careful timeline development to avoid submission delay
- Potential delay to MAA submission/validation if company needs less than 3 months to finalise submission dossier after last CSR becomes available

Full compliance check at time of PIP completion for SPC extension

- Covered by Articles 24, 28(3) and 36
- Inclusion of compliance statement in the MA to confirm eligibility
- Importance timely availability of opinion & statement
- Appeal mechanism should be available

Future areas for discussion for compliance check

1. Administrative vs Scientific nature - judgment on scientific validity in case of deviations

2. Roles of EMEA staff/NCA vs PDCO involvement

3. Possibility of shortened/abbreviated timelines (during validation or prior to submission) vs 60 Day process

4. Modification processes required prior to compliance check

5. PDCO opinion - timeliness of grant ; potential for challenge or reexamination ; Use of opinion for SPC extensions (e.g Art 29)

Next steps

- Pragmatic implementation required to meet the objectives and avoid delays
- Industry is very willing to work with EMEA on a procedure that uses resources in the best way
- EMEA has a key role in facilitating this pragmatic approach

Questions ?

Back up slides

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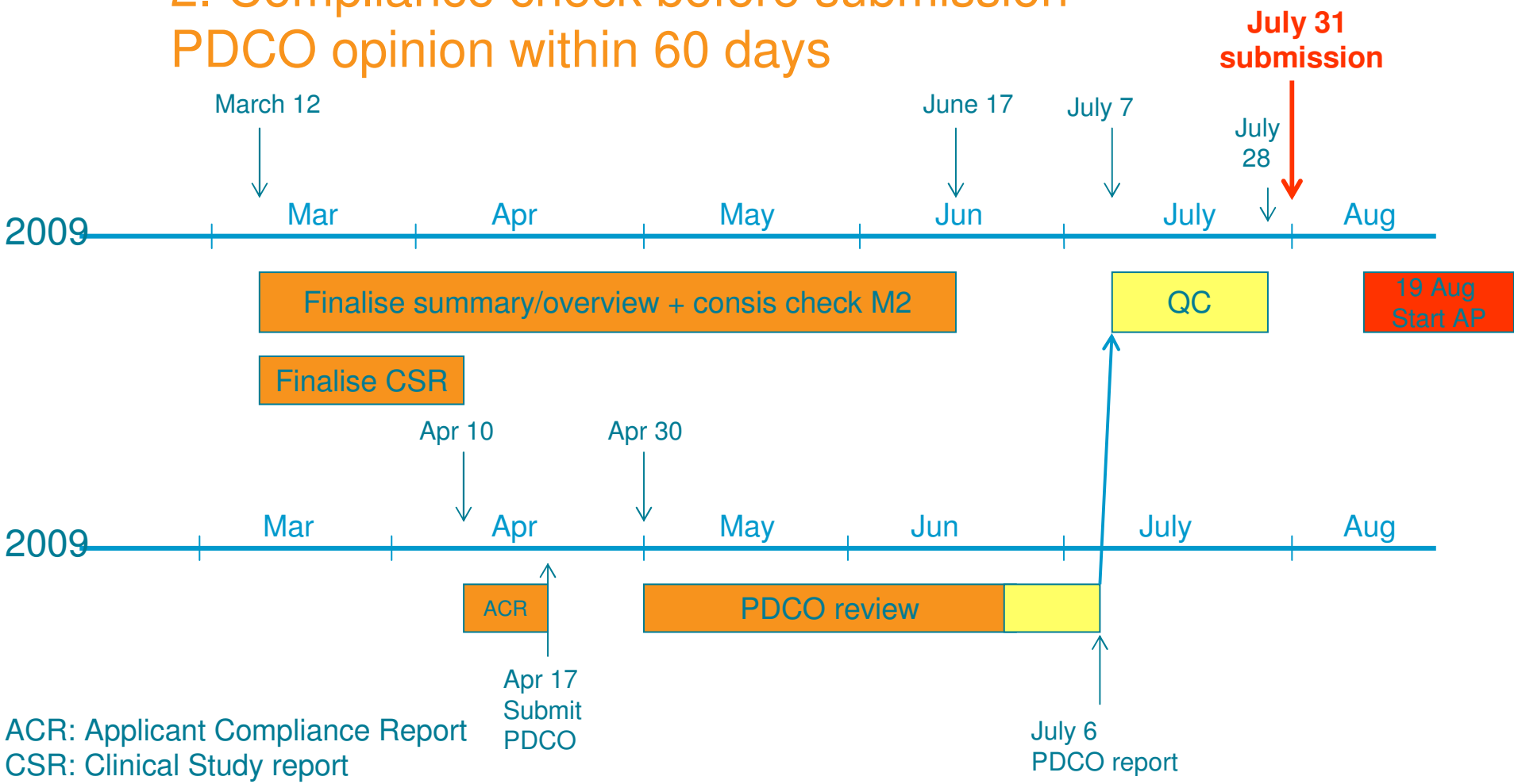
PDCO opinion within 60 days



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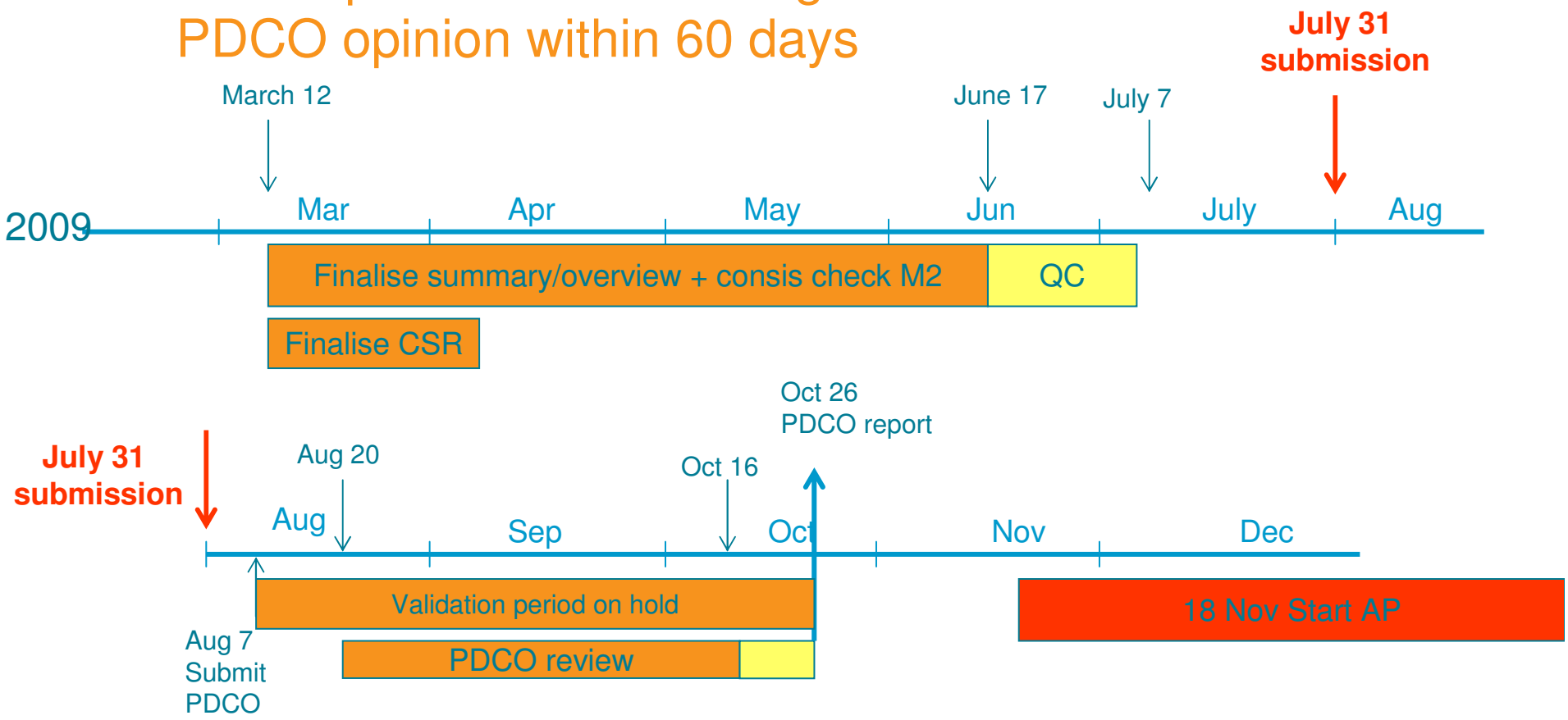

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