EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

MAH compliance with PRAC signal recommendations for PI update of CAPs

PRAC recommendations May15-Apr16

10th Industry stakeholder platform – operation of EU pharmacovigilance

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Background

1st Compliance check of signal PRAC recommendations for PI update (Sep12-Apr15)

- All PRAC signal recommendations for PI update involving CAPs had been implemented
- Majority of variations submitted in compliance with required timeline
- Sequential submissions for generics led to delay in updates to their PI (up to **10 m**)

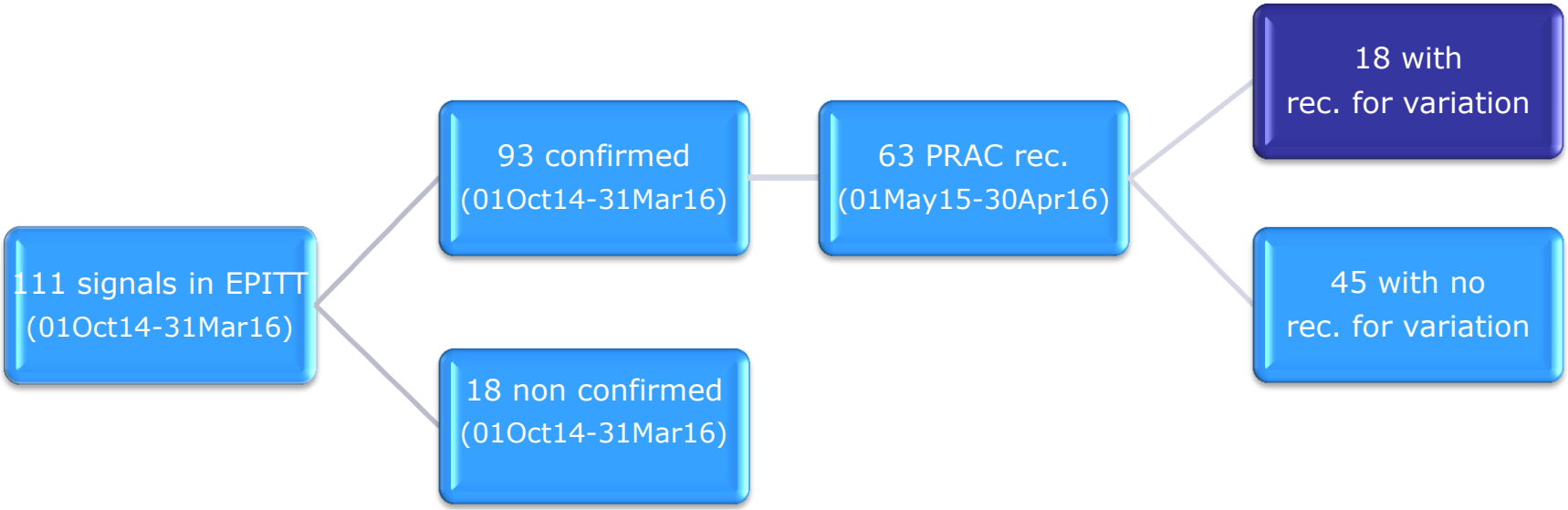
Sep 15: Concurrent submissions for generics

- Objective: to save time to implement PRAC recommendations in PI of generics
- Awareness:
  - published PRAC recommendations
  - Q&A on Signal Management
  - "What's new in Pharmacovigilance - QPPV update" sent to all EU QPPVs
  - EGA-EMA Annual bilateral meeting (27Jan16)

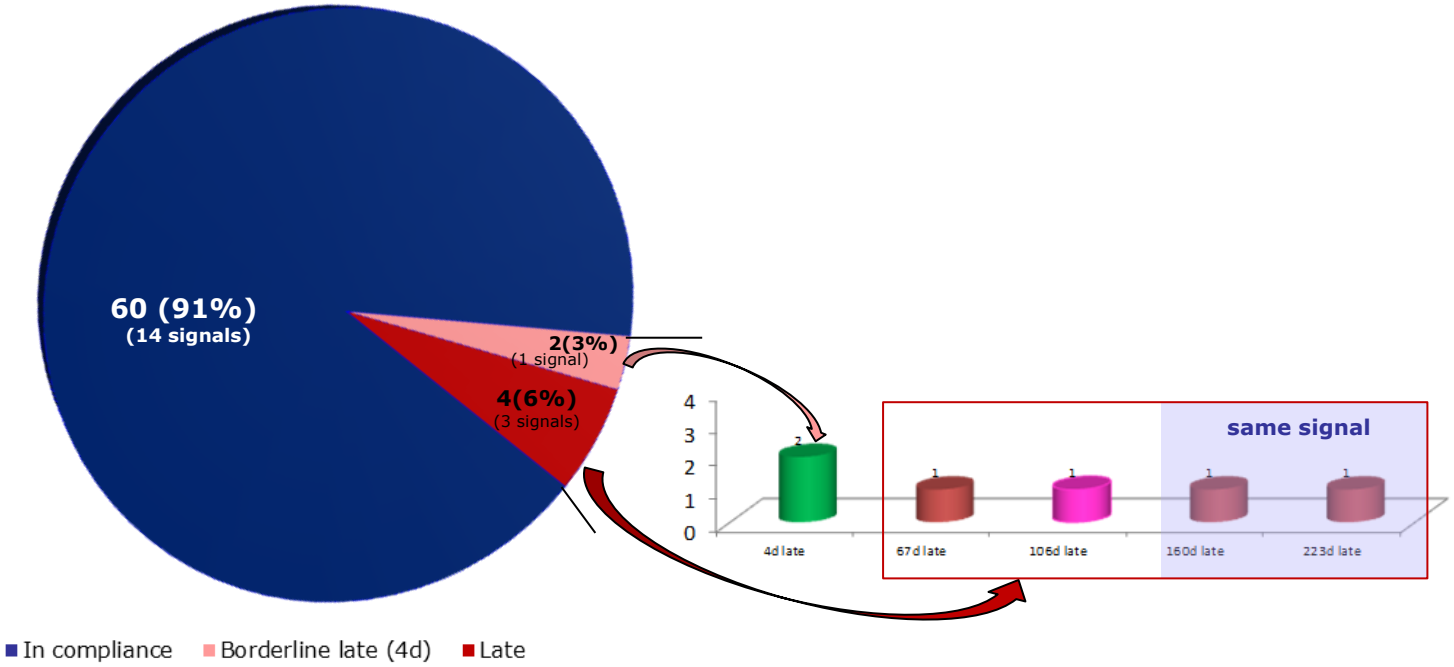
Current compliance check

- **Objective**: to check level of MAH compliance with PRAC recommendations for PI update in the context of signal assessment
- **Timeframe:** PRAC recommendations between May 2015 - Apr 2016
- **Scope**: Only PRAC recommendations for substances contained in CAPs
- **Sources**: SIAMED (records on variations for CAPs) + EPITT (records on signals) + ad-hoc liaison with relevant functions for clarifications

Records in EPITT



Submission of variations



Findings

- Generic MAHs submitted variations sooner (concurrent submission):
  - within the same timeline (1-3m) as Innovator (previously up to 10m after PRAC recommendation*)*
  - during first 4 m (subsequent submissions) 1 generic MAH submitted in compliance but ~ 1 m later than the deadline for Innovator ⟹ *This extra-time is now saved with concurrent submissions*

- Delayed submissions:
  - mainly generics (apart from 1 Innovator, borderline). 6 variations (4 signals), 3 of which from same MAH; the other 3 for 3 different MAHs
  - Reason: not aware of implementation of concurrent submission and awaiting for notification from EMA

Conclusions

- variations for all PRAC recommendations for PI update for CAPs have been submitted
  - **91% (= 60 variations)** submitted **within** the required timeline (e.g. 30, 60 or 90 days)
  - **9% (= 6 variations)** submitted **late**. Of those:
    - 1/3 (= 2 variations, 1 signal) borderline for compliance (only 4 d late)
    - 2/3 (= 4 variations, 3 signals) later than 2 m after recommended timeline, majority from the same MAH
- quicker implementation of PI update for generics

- next compliance check in 2017 (PRAC recommendations from May 2016 to April 2017)

Abbreviations

- CAP: Centrally Authorised Product
- EMA: European Medicines Agency
- EPITT: European Pharmacovigilance Issues Tracking Tool
- EU: European Union
- MAH: Marketing Authorisation Holder
- PI: Product Information
- PRAC: Pharmacovigilance Risk Assessment Committee
- QPPV: Qualified Person responsible for Pharmacovigilance

Thank you for your attention

Further information

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