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PSUSA procedure – EURD list & submission aspect

3rd Industry Stakeholder Platform - operation of EU pharmacovigilance legislation

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EURD list – living document

- Key instrument to regulate timing of submission of PSURs
- Allows for planning by MAHs, NCAs, and EMA
- Initial list compiled in 2011/2012 - extensive work was done by EMA and NCAs with valuable input from MAHs



» List is not set in stone – monthly updates on EMA website after consultation of PRAC and adoption by CHMP/CMDh

Granularity and Periodicity Advisory Group

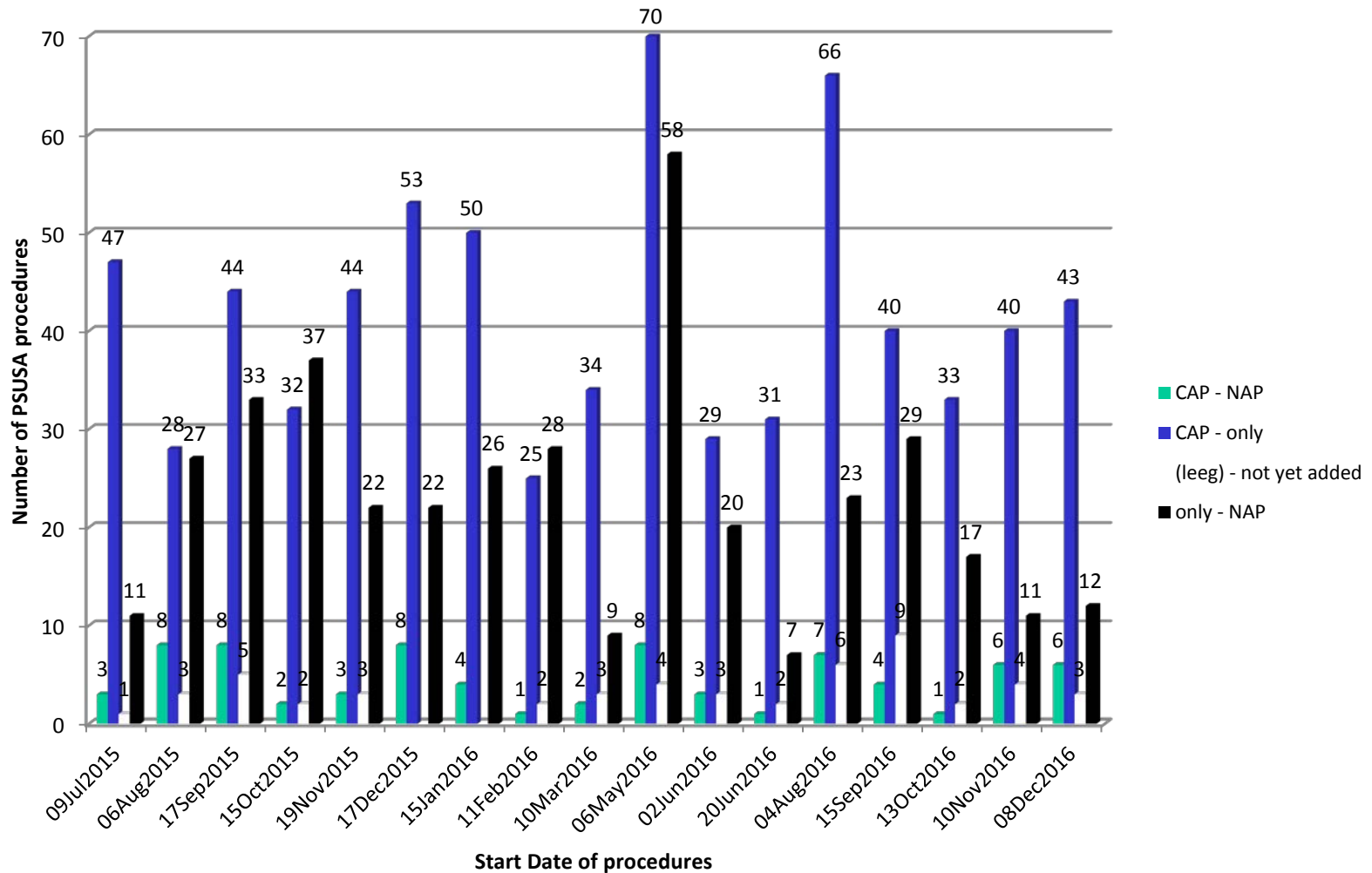
- To support PRAC, the Granularity and Periodicity Advisory Group (GPAG) has been established
- GPAG is composed of PRAC delegates, PSUR WS WP members, and EMA staff and:
 - provides advice to PRAC for the monthly review and update of the EURD list;
 - reviews upcoming procedures with a view to apply a risk based approach in defining periodicity and scope of the PSUSA procedures;
 - develops guidance and criteria to set the periodicity, based on scientific judgment taking into account the B/R profile of substances and other regulatory tools to monitor and review the safety and the B/R profile.

EURD list – update of ongoing work

- Mapping of EURD list entries with active substances in Article 57 database (e.g. salt forms, combination products)
- Review of the need to maintain current requests for submission of generic PSURs for certain substances
- How to deal with old and new products covered by one EURD list entry? (e.g. IVIG products)
- Consideration of workload aspects: both capacity of NCAs and PRAC plenary meeting

EURD list – workload estimation

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EURD list – workload aspects

- Reviewing possibilities to move forward start date of some procedures (without affecting DLP and submission date)
- Investigating whether some DLPs can be shifted (a bit) ahead or backwards:
 - international harmonisation will be respected
 - MAHs be contacted by EMA
- Review periodicity of active substances contained in more mature products – scientific judgment



Submission of PSURs for NAPs until repository is available

- Submission of PSURs for NAPs to NCAs is mandatory as per legislative requirements
- Submission of PSURs for NAPs to EMA is not mandatory but highly desirable
- Submissions should be in English language

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