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Pilot of MAH signal detection in EudraVigilance

13th Industry Stakeholder Platform – operation of EU pharmacovigilance

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Background

- Commission Implementing Regulation (EU) No 520/2012 requires MAHs to continuously monitor EV data and inform regulatory authorities of validated signals.
- Regulatory guidance on EV monitoring by MAHs and reporting processes for detected signals (including standalone notifications) is available in GVP IX rev. 1 on Signal Management.
- To streamline the implementation of these requirements, EMA and the European Commission have agreed on transitional arrangements:
  - ✓ *pilot period of one year starting on 22 February 2018,*
  - ✓ *focussing on limited number of active substances (based on additional monitoring list).*

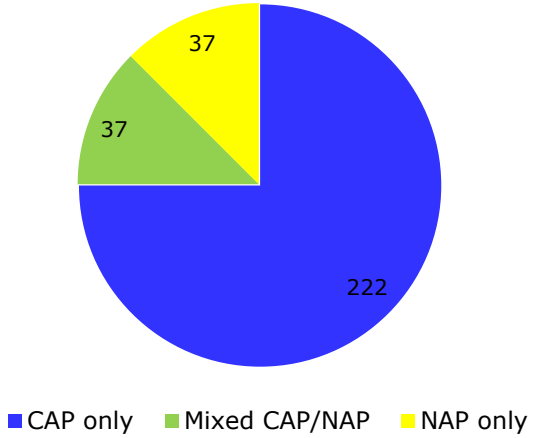
Substances and combinations included in the pilot

- ✓ The pilot list is available on the EMA Signal Management webpage since October 2017.
- ✓ It contains all substances/combinations that were included in the additional monitoring list in force at the time (rev. 49).
- ✓ All medicinal products containing substances/combinations mentioned in the pilot list are part of the pilot, regardless of whether or not the medicinal products themselves are subject to additional monitoring.
- ✓ The pilot list is the reference for the pilot and is essentially static, i.e. changes in additional monitoring status occurring after October 2017 will not affect the pilot.

Some features of the pilot list

296 substances
(249 single ingredients, 47 FDCs)
398 MAHs (QPPVs)

Authorisation procedure

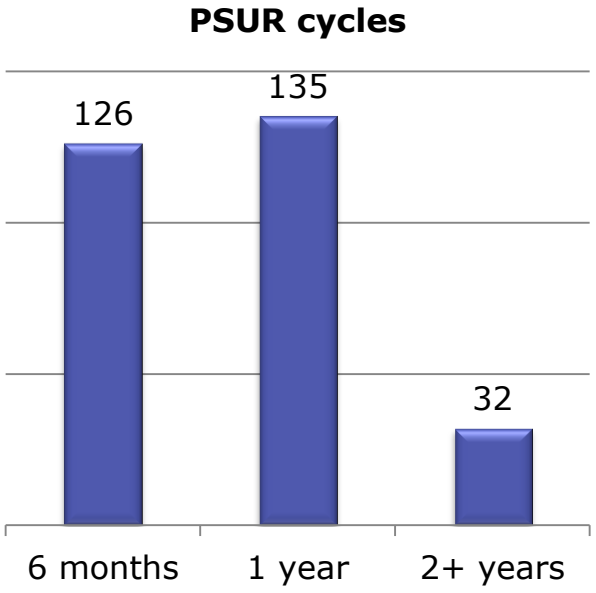


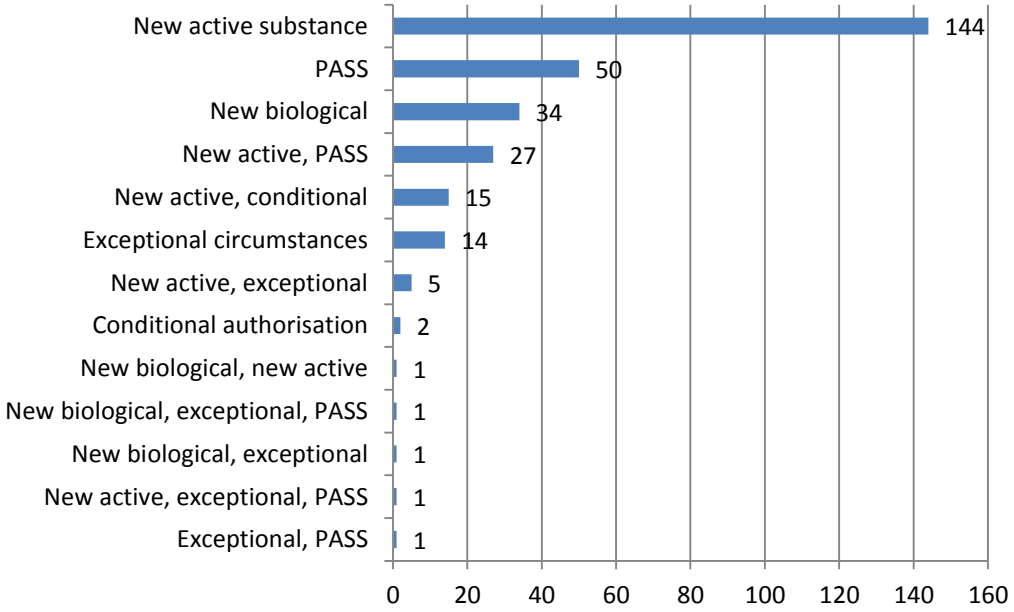
Legal basis

Full application	282
Generic	31
Well-established use	30
Informed consent	23
Hybrid	18
Fixed combination	13
Biosimilar	11
Article 126a	11
Article 58	1

Source: Article 57 database

Some features of the pilot list (2)



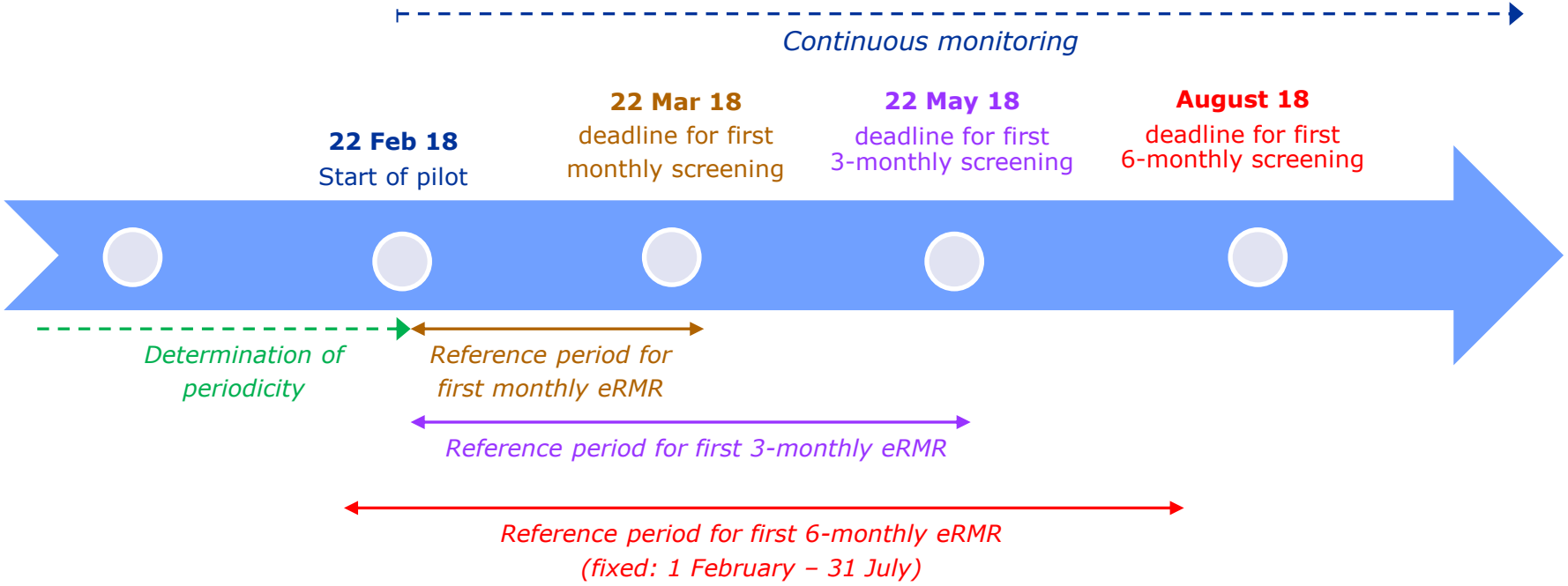


Source: EURD list (Jan 2018)

EudraVigilance monitoring

- 22 February 2018 was the start of the continuous monitoring of EV data for MAHs involved in the pilot.
- By that date, MAHs should have:
  - ✓ identified the 'active substance high level' corresponding to their product using the 'active substance grouping' EVDAS report
  - ✓ determined and documented the periodicity at which they plan to monitor EV data for each of their products in the pilot, using a risk-based approach.
- In line with GVP IX, periodicity may be every 6 months for the 'PASS only' substances of the pilot list, but should in principle be more frequent for others.
- The chosen periodicity determines the date of the first screening, which should cover DECs with new cases reported to EV on or after 22 February 2018.

First eRMR screenings for substances in the pilot



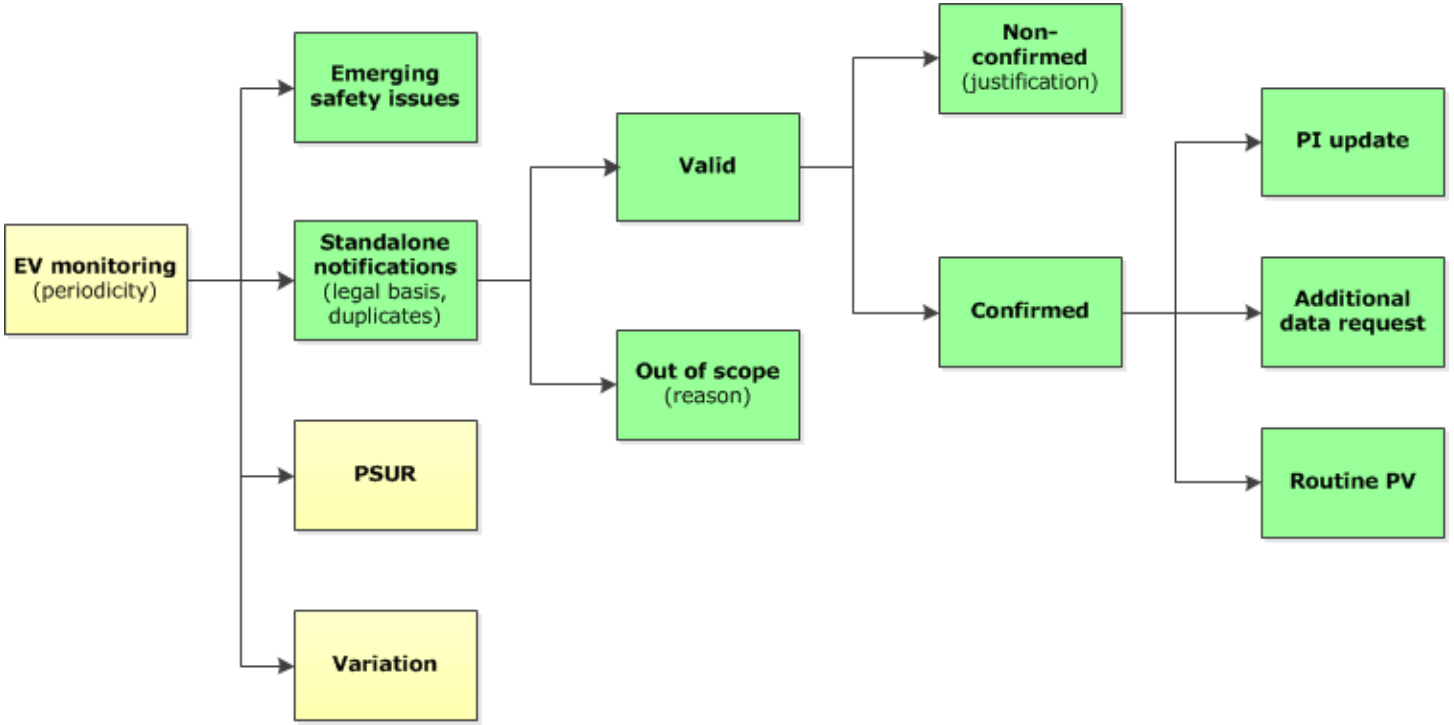
Evaluation of the pilot: main objectives

- Informed impact assessment of involvement of MAHs in EV monitoring
- Insight into:
  - ✓ resource implications
  - ✓ important safety issues detected
  - ✓ EV tools and areas of guidance / process to be further clarified or streamlined
  - ✓ duplication of signals for substances with several MAHs

Evaluation of the pilot: limitations

- Essentially descriptive
- Limited data on full signal lifecycle, especially for substances monitored on a 6-monthly basis
- Limited data on generics, NAPs, products with long PSUR cycles
- Industry input - possibly through survey - on some areas will be needed, e.g. signals submitted directly in variations or PSURs

Evaluation of the pilot: main metrics



Next steps

- Next phase beyond first pilot year will be subject to early discussions with the European Commission.
- Industry stakeholders to be informed of next phase in Q4 2018.

Any questions?

Further information

[Insert relevant information sources or contact details as applicable.]

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