EMA
EUROPEAN MEDICINES AGENCY

EMA/FDA parallel scientific advice

Vladimír Pucovský
Scientific administrator

Parallel scientific advice (PSA)

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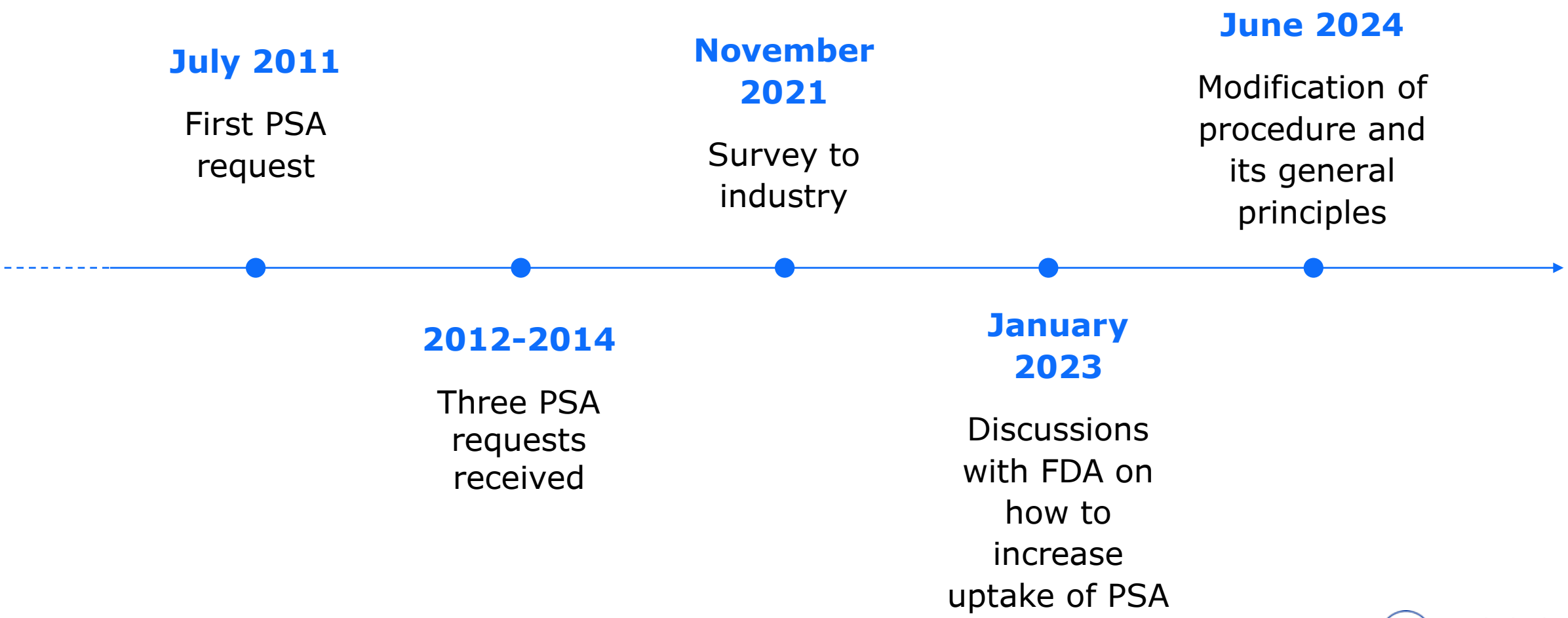
PSA goals

- To increase dialogue between the two agencies and applicants from the beginning of the lifecycle of a new veterinary medicinal product
- To provide a deeper understanding of the bases of regulatory decisions
- To optimise product development
- To avoid unnecessary testing replication or unnecessary diverse testing methodologies

A mechanism for EMA assessors and FDA reviewers to **concurrently exchange** with applicants their views on scientific issues during the development phase of new veterinary medicinal products

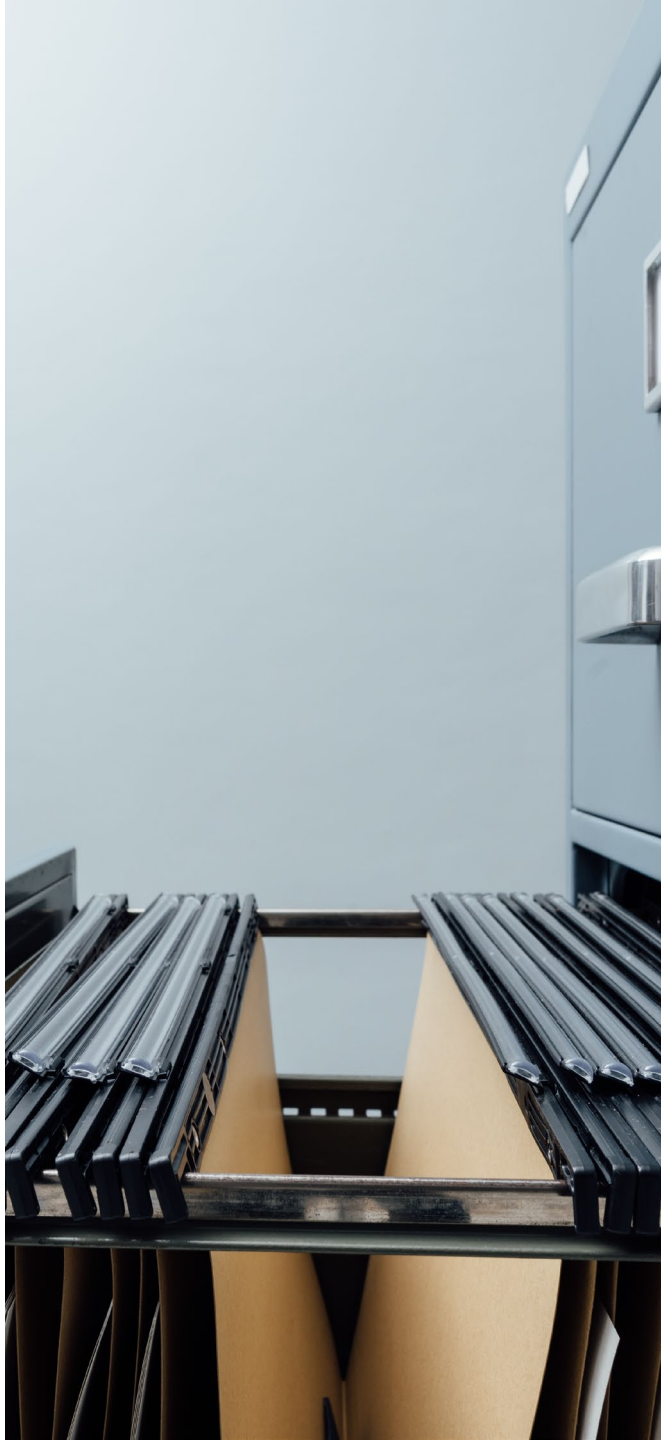
PSA history



Process and procedure

- **Voluntary** - application to both EMA and FDA, both must agree
- Questions on specific scientific issues for a VMP intended for **both jurisdictions**
- **90-day timetable** (usually)
- **Confidentiality**, based on agreement between EC, EMA and FDA
- Applicant participates in a joint **trilateral meeting. (NEW)**
- **Two advices** issued (each agency provides their own advice)
- Any applicable **fees remain unaffected** by PSA.

Goal: to achieve harmonisation and convergence



PSA: myths and facts

Myth	Fact
1. PSA makes development design difficult without ignoring the advice of one of the agencies. An applicant gets more from just seeking guidance from each agency independently.	**1. Not accurate.** Two scientific advices issued; each agency provides its own advice.
2. The outcome would be the lowest common denominator or highest restrictions.	**2. The opposite:** The aim is to achieve harmonisation and convergence. If not possible, an explanation is provided.
3. The advice will end up being more restrictive (aligning with the requirements of the stricter agency results in holding the entire world to a stricter standard).	**3. The opposite:** Higher chance to achieve harmonisation and convergence of advice when both agencies talk to each other during PSA.
4. Third agencies may request PSA documentation, and this could create hurdles for global registrations.	**4. Incorrect.** The data are shared between EMA and FDA, but not with third agencies.

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Thank you

vladimir.pucovsky@ema.europa.eu

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Additional information

- The application procedure for PSA can be found in Section 9 of the Guidance for applicants.
- The fee for PSA is the same as for regular scientific advice; please see Annex II questions and answers – Fees, charges and remuneration for assessment procedures and services relating to veterinary medicinal products and Fees payable to the European Medicines Agency.
- Protocol assistance falls into the scope of scientific advice.
- PSA is valid only for products regulated by EMA or FDA. The ***USDA does not operate*** this procedure.