



Session 2

Use of regulatory data in research projects: spotlight on the assessment report

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Use of regulatory data in research projects: spotlight on the assessment report

Co-moderators



Marjon Pasmooij

Co-chair European Platform
for Regulatory Science
Research

MEB



Adam Hacker

Co-chair European Platform
for Regulatory Science
Research

CEPI

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Use of regulatory data in research projects: spotlight on the assessment report

Introduction to the topic

Marjon Pasmooij



GOOD
MEDICINES
USED
BETTER

What is an EPAR?

- European public assessment report (EPAR) for every human or veterinary medicine application that has been granted or refused a marketing authorisation.
- Not a single document -> several components, including a core set of regulatory documents.

Section	Type of information
Overview	Public-friendly overview in question-and-answer format.
Authorisation details	Key details about the product and the <u>marketing authorisation holder</u> .
<u>Product information</u>	<u>Package leaflet</u> and <u>summary of product characteristics</u> ; <u>labelling</u> ; list of all authorised presentations; pharmacotherapeutic group; therapeutic indications.
Assessment history	Public assessment report for the initial authorisation; public assessment report(s) for any <u>variation concerning major changes to the marketing authorisation</u> ; orphan maintenance assessment report or withdrawal assessment report (as of 17 January 2018); tabulated overview of procedural steps taken before and after authorisation.

Where can you find them?

- Human medicines

This search looks for keywords in all of the website's content. You can also [download all of our medicine data](#). More help: [search tips](#) ✕

Filter by

☒ Include documents (44702)

Categories

☐ Corporate (8104)

☐ Herbal (3327)

☒ Human (61196)

☐ Veterinary (8030)

Medicine name

Show all +

Active substance / international non-proprietary name (INN) / common name

Search results (61196) Sort by **Newest first** ▾

Remove all filters ● Include documents ● Human ●

Matever : EPAR - Procedural steps taken and scientific information after authorisation (archive)

English (EN) (203.52 KB - PDF)
First published: 02/12/2011 Last updated: 16/05/2025 [View](#) ⓘ

Matever : EPAR - Product Information

English (EN) (1.32 MB - PDF)
First published: 14/10/2011 Last updated: 16/05/2025 [View](#) ⓘ

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Home > Medicines > Fintepla

Fintepla
fenfluramine

Medicine Human

Share RSS

Authorised
This medicine is authorised for use in the European Union

Page contents

Overview

Product information

Product details

Application under evaluation CHMP opinion **European Commission decision**

Overview

Page contents

Overview

Product information

Product details

Authorisation details

Assessment history

News on Fintepla

More information on Fintepla

Initial marketing authorisation documents

Fintepla : EPAR - Public assessment report
Adopted
Reference Number: EMA/639853/2020 Corr.

English (EN) (1.89 MB - PDF)
First published: 08/01/2021 Last updated: 29/04/2021 [View](#) ⓘ

Fintepla : Orphan maintenance assessment report (initial authorisation)
Adopted
Reference Number: EMADOC-1700519818-578199

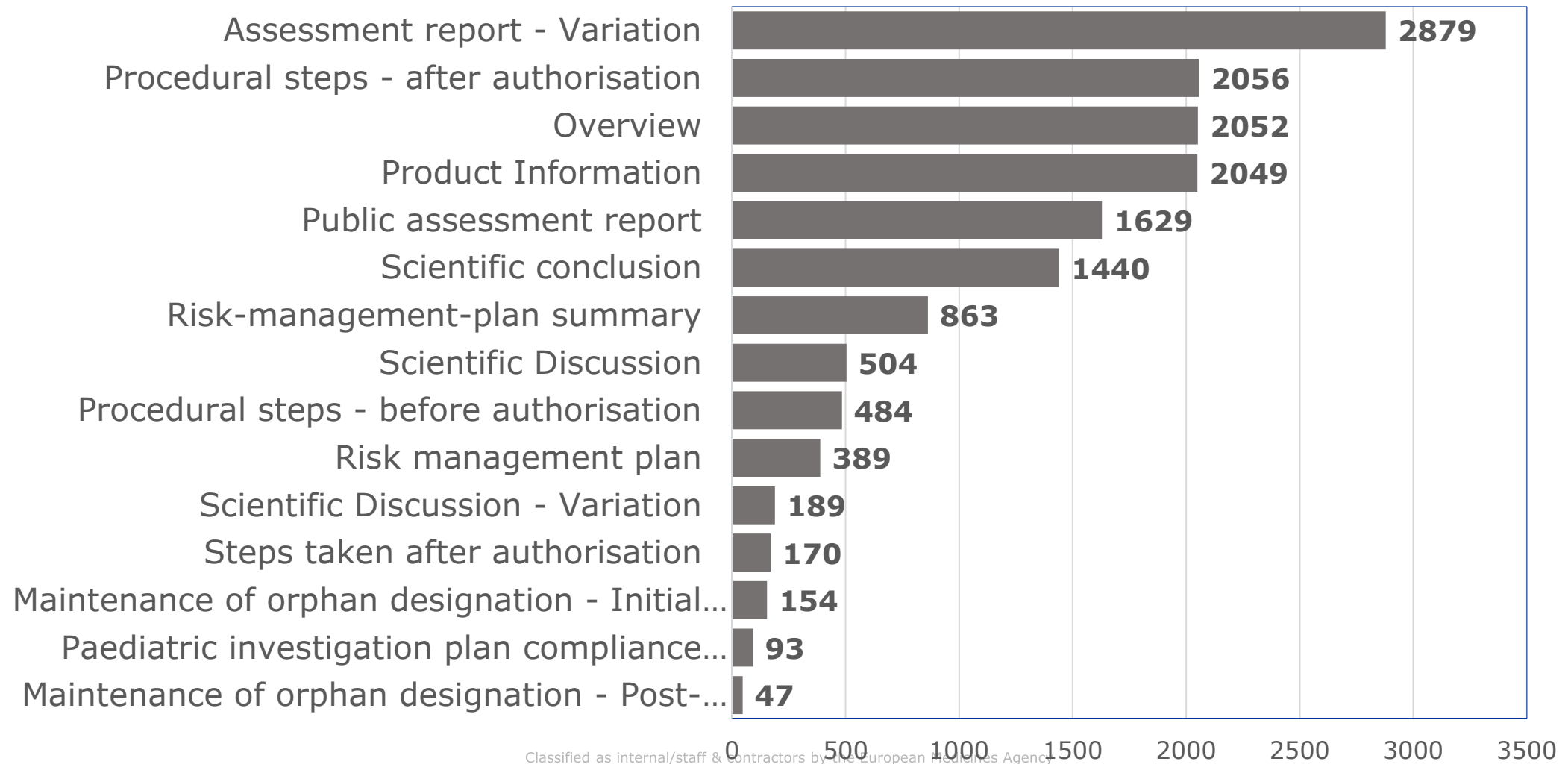
English (EN) (719.51 KB - PDF)
First published: 08/01/2021 [View](#) ⓘ

CHMP summary of positive opinion for Fintepla
Adopted
Reference Number: EMA/CHMP/510338/2020

[Back to top](#)

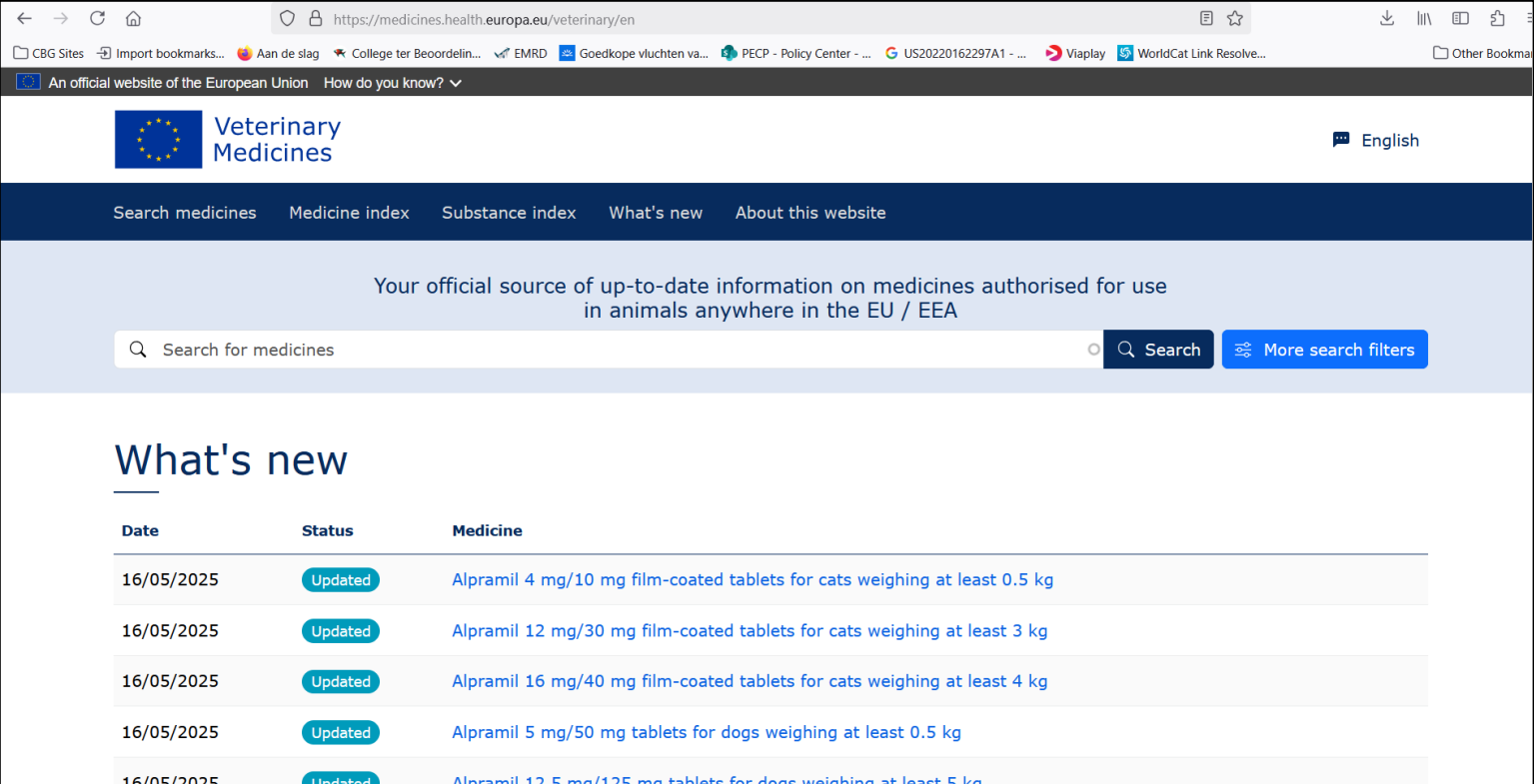
How many documents?

Number of EPARs per type



Where can you find them?

- Veterinary medicines



The screenshot displays the official website of the European Medicines Agency (EMA) for Veterinary Medicines. The page features a dark blue header with the EMA logo and the text 'Veterinary Medicines'. Below the header is a navigation bar with links: 'Search medicines', 'Medicine index', 'Substance index', 'What's new', and 'About this website'. A search bar is prominently displayed with the text 'Search for medicines' and a 'Search' button. Below the search bar, the text reads: 'Your official source of up-to-date information on medicines authorised for use in animals anywhere in the EU / EEA'. The 'What's new' section is highlighted, showing a table of updated medicines.

Date	Status	Medicine
16/05/2025	Updated	Alpramil 4 mg/10 mg film-coated tablets for cats weighing at least 0.5 kg
16/05/2025	Updated	Alpramil 12 mg/30 mg film-coated tablets for cats weighing at least 3 kg
16/05/2025	Updated	Alpramil 16 mg/40 mg film-coated tablets for cats weighing at least 4 kg
16/05/2025	Updated	Alpramil 5 mg/50 mg tablets for dogs weighing at least 0.5 kg
16/05/2025	Updated	Alpramil 12.5 mg/125 mg tablets for dogs weighing at least 5 kg

What are characteristics of EPARs?

- Reflect scientific conclusions at the end of the assessment process
- Providing insights in regulatory thinking – Transparency
- Highly structured documents
- Structure can evolve over time

EPAR – Public Assessment Report

1. Background information on the procedure

2. Scientific discussion

- 2.1. Problem statement
- 2.2. Quality aspects
- 2.3. Non-clinical aspects
- 2.4. Clinical aspects
- 2.5. Clinical efficacy
- 2.6. Clinical safety
- 2.7. Pharmacovigilance
- 2.8. Product information

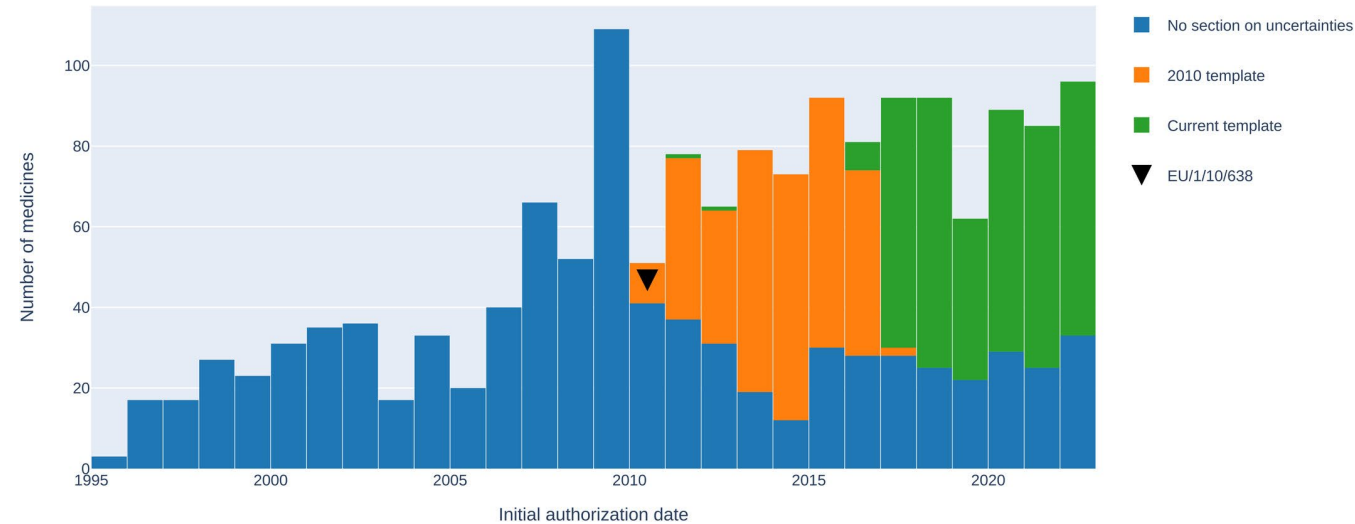
3. Benefit-Risk Balance

- 3.1. Therapeutic Context
- 3.2. Favourable effects
- 3.3. Uncertainties and limitations about favourable effects
- 3.4. Unfavourable effects
- 3.5. Uncertainties and limitations about unfavourable effects
- 3.6. Effects Table
- 3.7. Benefit-risk assessment and discussion
- 3.8. Conclusions

4. Recommendations

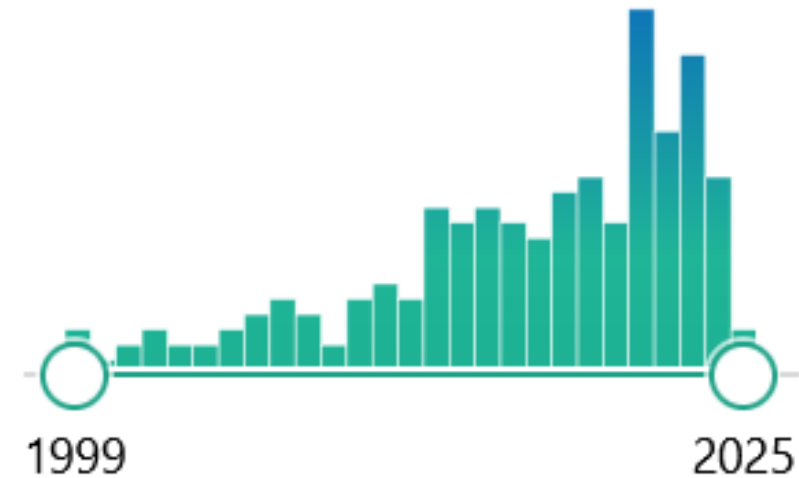
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EPARs as a tool in Regulatory Science Research

- Search on “European Public Assessment Report” OR “European Public Assessment Reports” (in English)
- 164 articles PubMed
- *Oncology & hematology*
- *Patient-centered outcomes*
- *Pharmacovigilance & safety*
- *Clinical trial design*
- *Real-world evidence*
- *Biosimilars & biologics*
- *Rare diseases & orphan medicines*
- 10 *Veterinary*



Contents lists available at [ScienceDirect](#)

Biologicals

journal homepage: www.elsevier.com/locate/biologicals



Research paper

The contribution of field efficacy studies to the evaluation of applications for veterinary vaccines evaluated through the European Union centralised authorisation procedure

David Mackay^a, Cristina Martin Jimenez^b, Faye Ioannou^c, Martin Illott^{d,*}

^a Brook Lodge, Rectory Lane, Niton, PO38 2AX, Isle of Wight, United Kingdom

^b Pen & Tec Consulting, S.L.U., Pl. Ausias March, 1, 4th Floor, D01, 08195, Sant Cugat Del Valles, Barcelona, Spain

^c European Commission, DG SANTE, Directorate F, Unit F2, Animal Health, Grange, Dunsany, Co Meath, Ireland

^d Australian Pesticides and Veterinary Medicines Authority, 102 Taylor Street, Armidale, NSW, 2350, Australia





Email address:
regulatory.science@ema.europa.eu

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