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

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HMA Heads of Medicines Agencies

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Introduction to the topic

Marjon Pasmooij

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What is an EPAR?

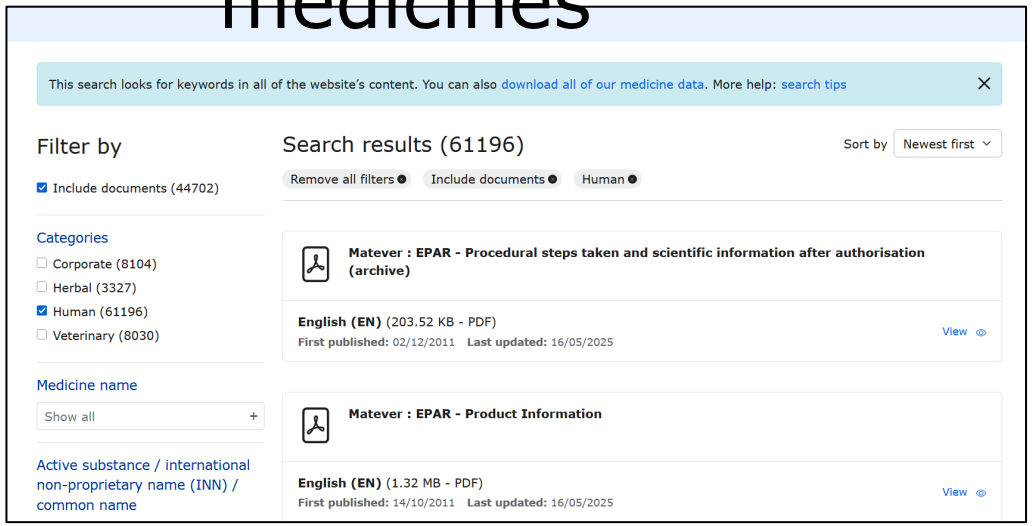
- European public assessment report (EPAR) for every human or veterinary medicine application that has been granted or refused a marketing authorisation.

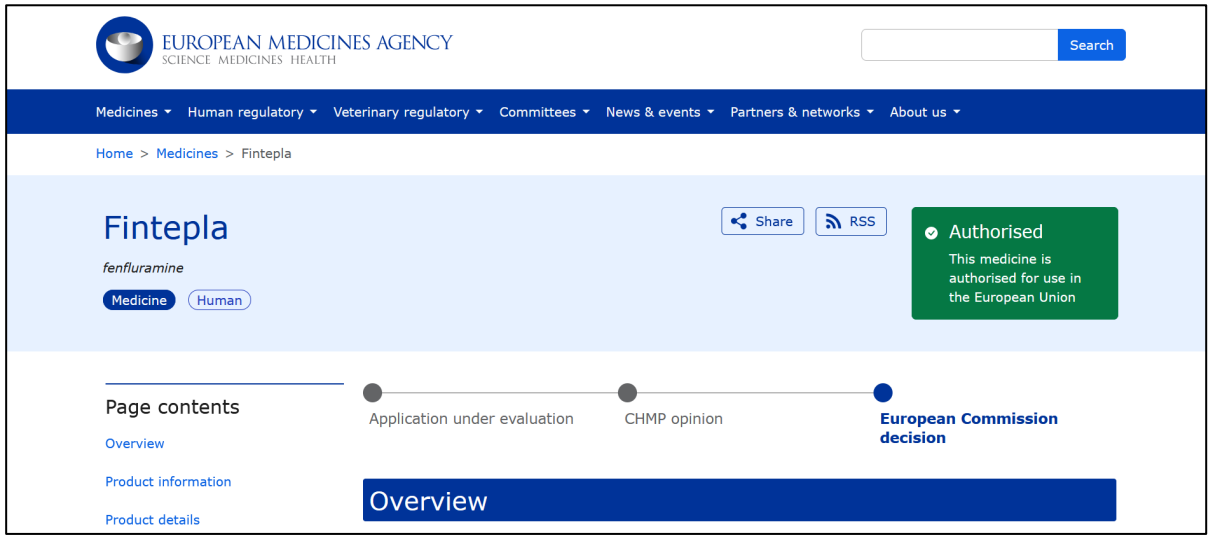
- Not a single document -> several components, including a core set of regulatory documents.

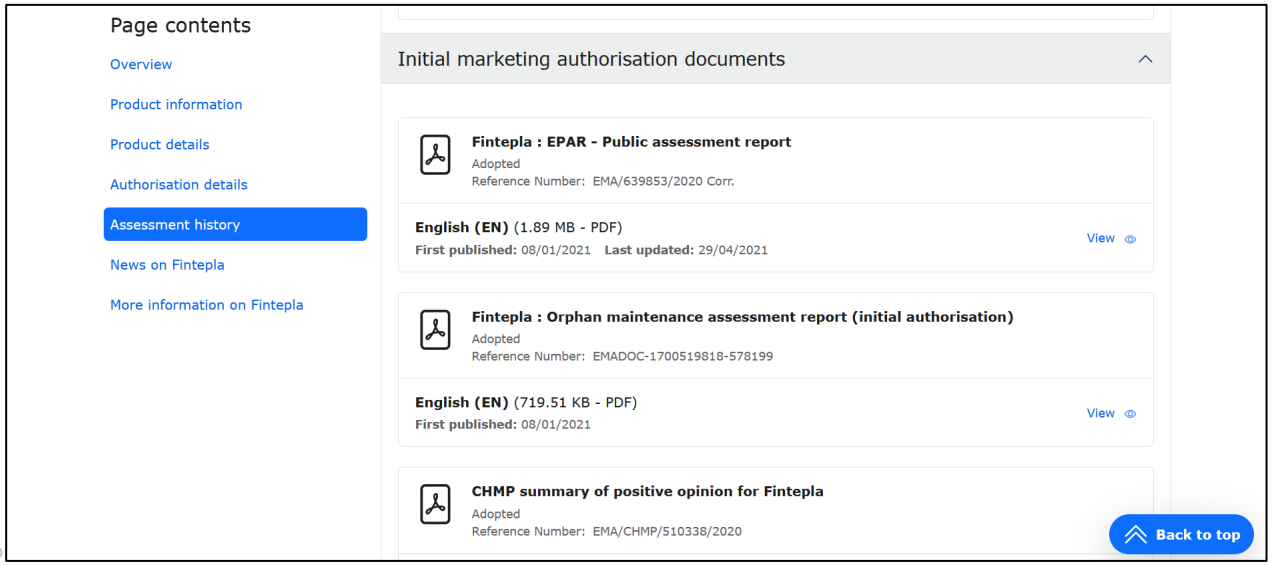
Section	Type of information
Overview	Public-friendly overview in question-and-answer format.
Authorisation details	Key details about the product and the marketing authorisation holder.
Product information	Package leaflet and summary of product characteristics; labelling; list of all authorised presentations; pharmacotherapeutic group; therapeutic indications.
Assessment history	Public assessment report for the initial authorisation; public assessment report(s) for any variation concerning major changes to the marketing authorisation; 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?

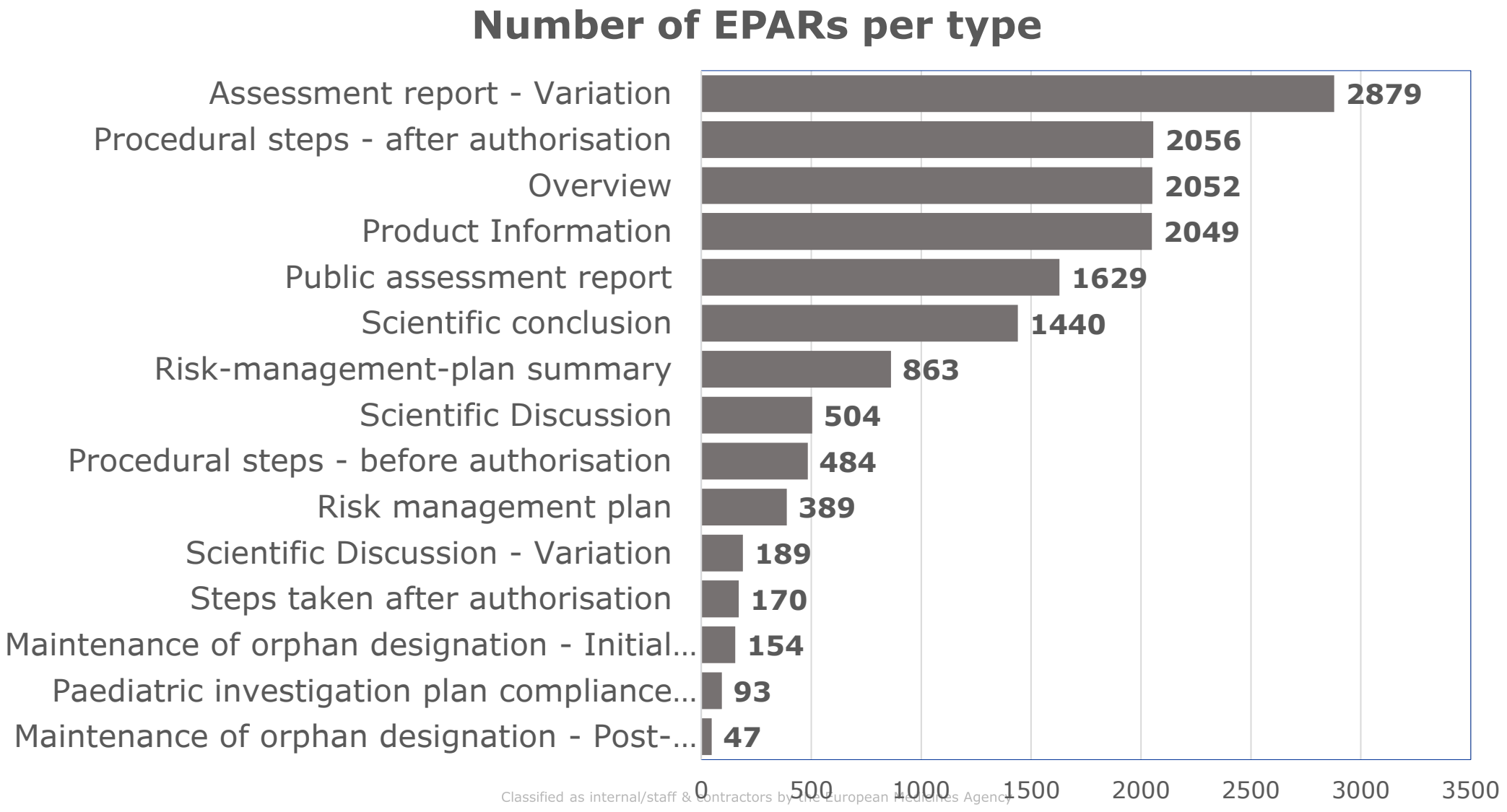
- Human medicines





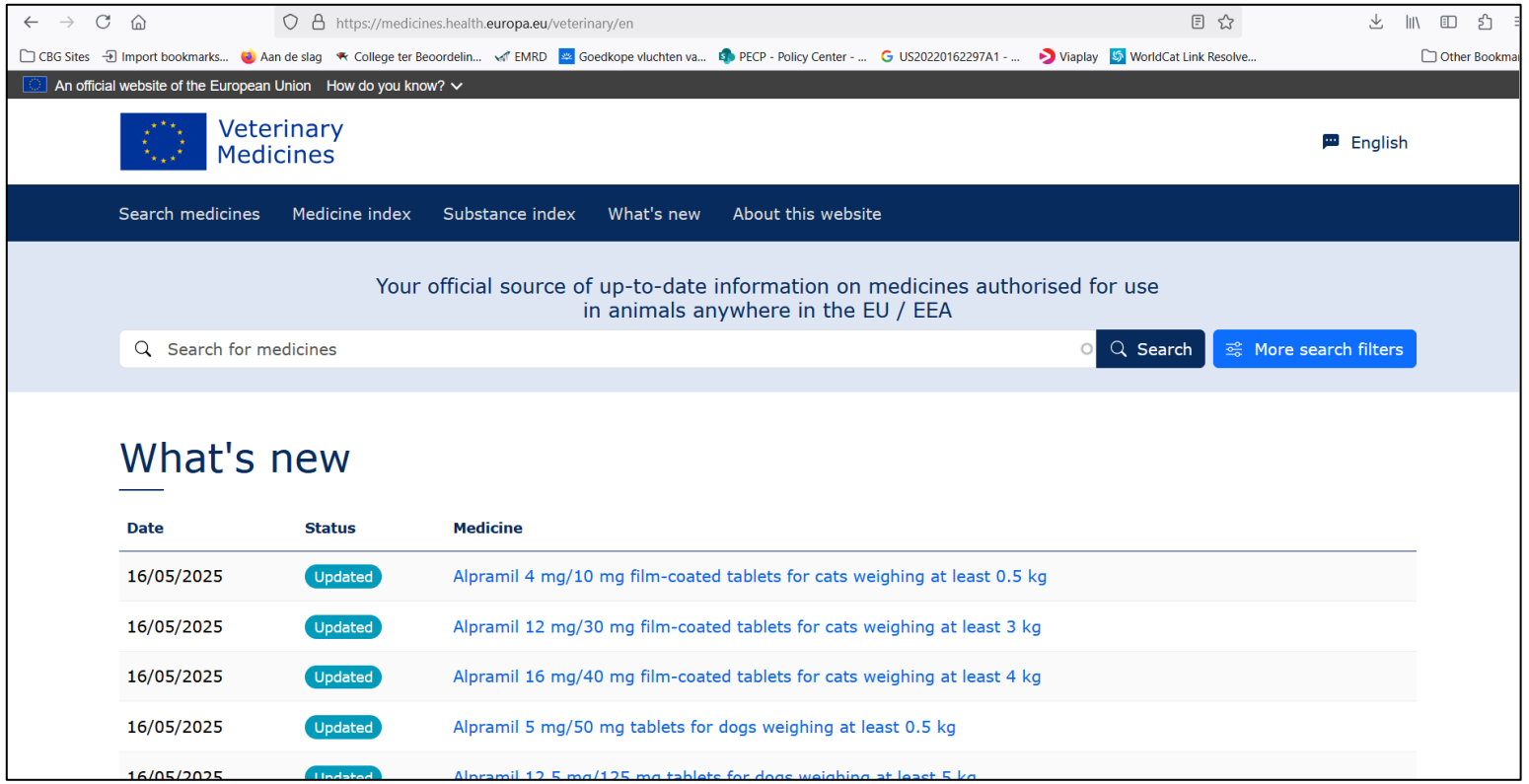


How many documents?



Where can you find them?

- Veterinary medicines



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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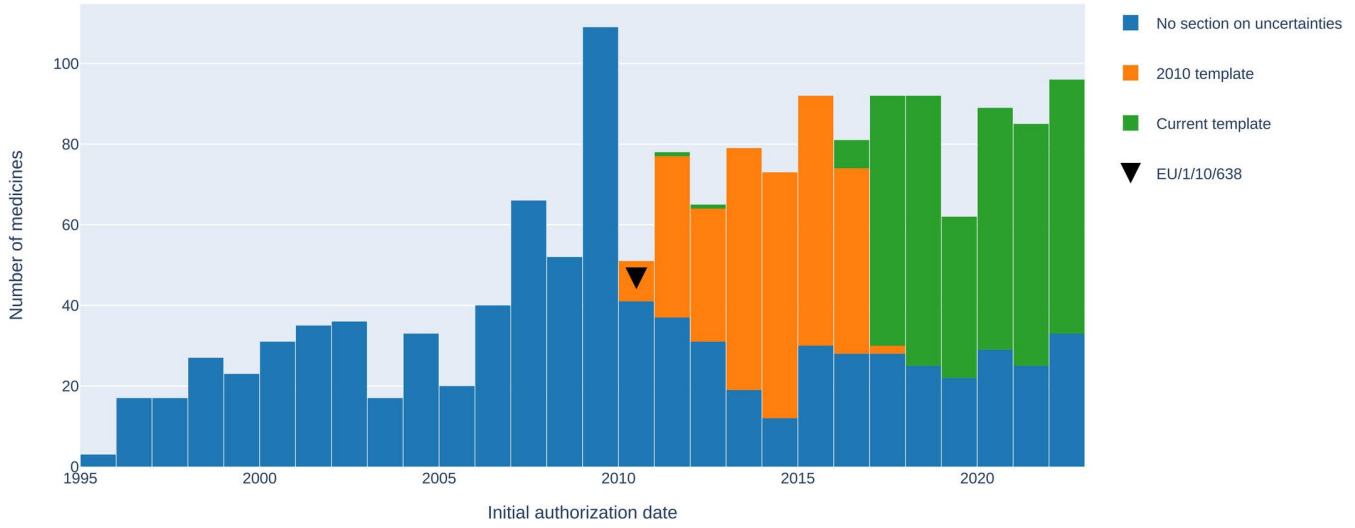


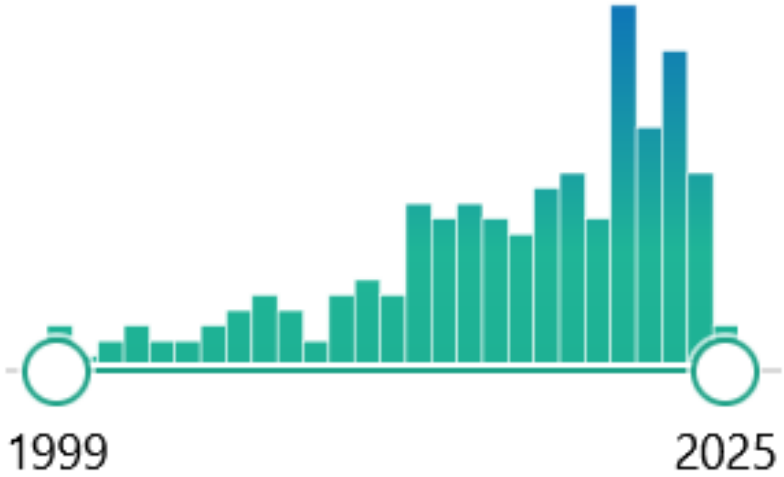
Verweij et al., 2024, Clin Pharmacol Ther

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*
- *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

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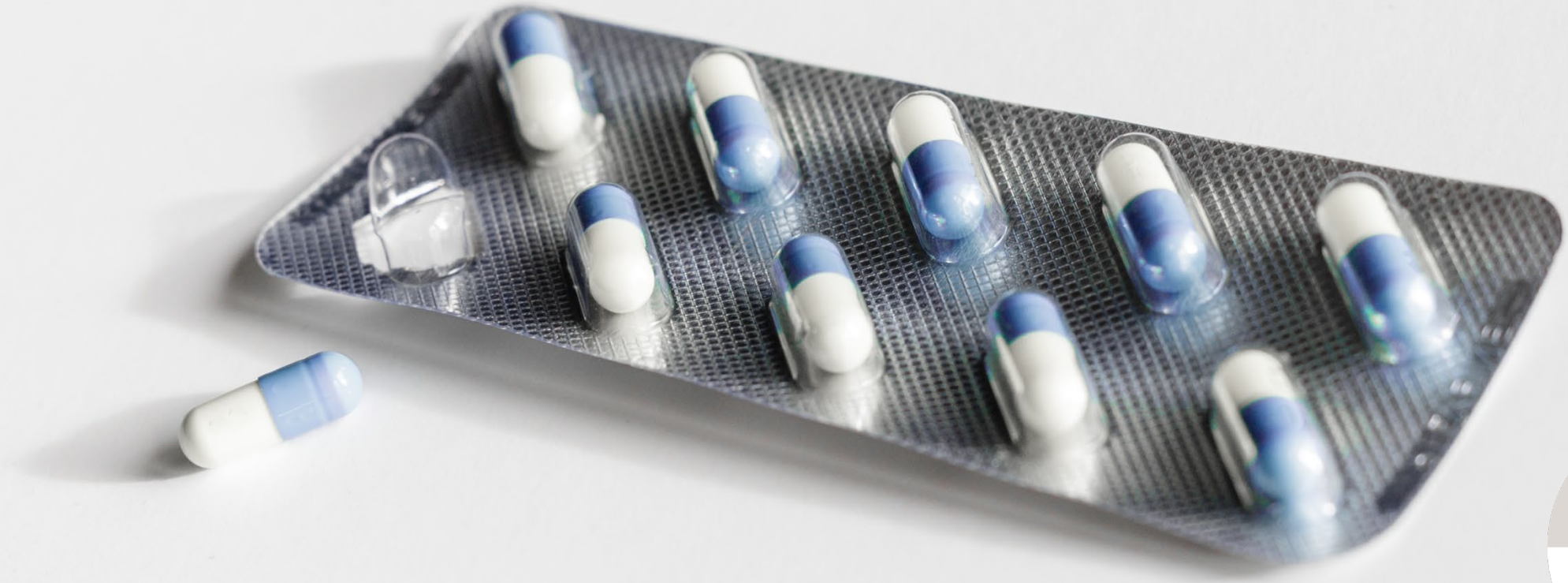

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