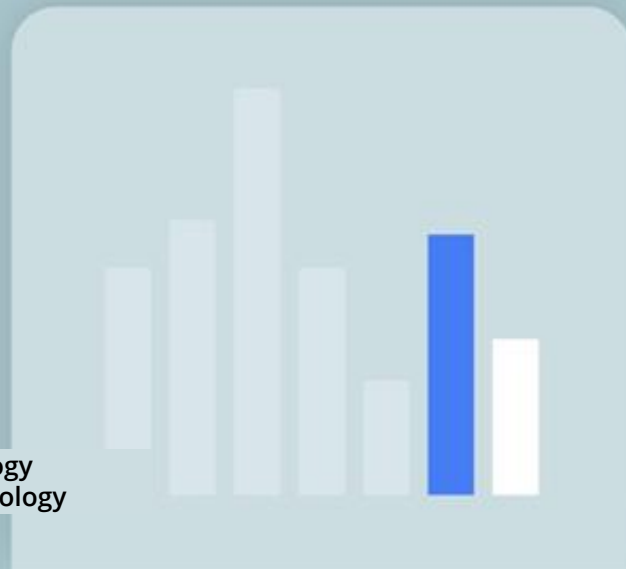
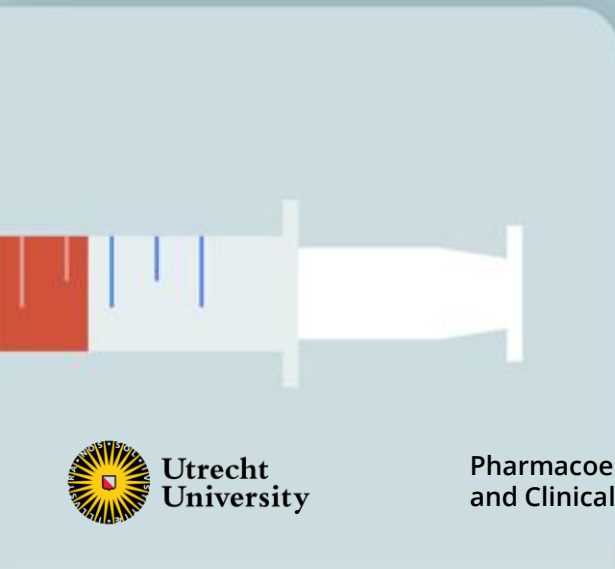


# The European Medicines Regulatory Database

An open science approach to regulatory science





Utrecht  
University

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M E B

MEDICINES  
EVALUATION  
BOARD

# The European Medicines Regulatory Database (EMRD)

Centralised and up-to-date regulatory data

Utrecht University:

Jarno Hoekman, Vincent Haverhoek

MEB:

Marjon Pasmooij, Stefan Verweij



# What is regulatory science?

The science of developing and validating new standards and tools to evaluate and assess the benefit-risk balance of medicines, in order to facilitate sound and transparent regulatory decision-making (Dutch Medicines Evaluation Board)

Three main objectives

- Evaluate and assess the benefit-risk balance (typically by regulators)
- Develop and validate standards, tools and approaches to assess quality, safety & efficacy
- Evaluate the medicine regulatory system and its effectiveness

# Studies evaluating regulation

Registries in European post-marketing surveillance: a retrospective analysis of centrally approved products, 2005–2013

Jacoline C. Bouvy<sup>1,2</sup> , Kevin Blake<sup>1</sup> , Jim Slattery<sup>1</sup> , Marie L. De Bruin<sup>2,3</sup> , Peter Arlett<sup>1</sup>  and Xavier Kurz<sup>1\*</sup> 

Regulatory watch

## Impact of scientific advice from the European Medicines Agency



[Matthias P. Hofer](#), [Christina Jakobsson](#), [Nikolaos Zafiropoulos](#), [Spiros Vamvakas](#), [Thorsten Vetter](#), [Jan Regnstrom](#)  & [Robert J. Hemmings](#)

## Evaluation of Companion Diagnostics in Scientific Advice and Drug Marketing Authorization Applications by the European Medicines Agency

Marc Maliepaard<sup>1,2\*</sup>, Priscilla Nibi<sup>1</sup>, Gabriëlla Nibi<sup>1</sup> and Anna M. G. Pasmooij<sup>1</sup>

<sup>1</sup> Dutch Medicines Evaluation Board (CBG-MEB), Utrecht, Netherlands, <sup>2</sup> Department of Pharmacology and Toxicology, Radboud University Medical Centre, Nijmegen, Netherlands



## Mining scientific advice reports on cell-based products: Insight into the nonclinical development program

Tineke van den Hoorn  | Tahira Nakchedi | A. Charlotte M.T. de Wolf | Anna M.G. Pasmooij | Jan Willem van der Laan  | Carla A. Herberts

## Use of Real-World Data and Evidence in Drug Development of Medicinal Products Centrally Authorized in Europe in 2018–2019

Sini Marika Eskola<sup>1,2</sup>, Hubertus Gerardus Maria Leufkens<sup>1</sup>, Andrew Bate<sup>3,4,5</sup>, Marie Louise De Bruin<sup>1</sup> and Helga Gardarsdottir<sup>1,6,7,\*</sup>






## European Conditional Marketing Authorization in a Rapidly Evolving Treatment Landscape: A Comprehensive Study of Anticancer Medicinal Products in 2006–2020

Lourens T. Bloem<sup>1,\*</sup> , Jasmin Schelhaas<sup>1,2</sup>, Lucía López-Anglada<sup>3</sup> , Carla Herberts<sup>2</sup>, Paula B. van Hennik<sup>2</sup> and Olli Tenhunen<sup>4,5</sup>

## More medicines for children: impact of the EU paediatric regulation

Sofia Nordenmalm,<sup>1</sup> Paolo Tomasi,<sup>2</sup> Chrissi Pallidis<sup>2</sup>

## Medication Adherence Measurement Methods in Registration Trials Supporting the Approval of New Medicines: A Cross-Sectional Analysis of Centralized Procedures in the European Union 2010–2020

Katerina M. Mantila<sup>1,2,3</sup> , Anna M.G. Pasmooij<sup>3</sup> , Christine Erikstrup Hallgreen<sup>1</sup> , Peter G.M. Mol<sup>2,3</sup>  and Job E.M. van Boven<sup>2,4,\*</sup> 

# Regulatory data

Needed to:

- Evaluate cohorts of medicines previously assessed by the European Medicines Agency
- Evaluate the prior use of certain tools and the evidence generated by them
- Evaluate how evidence has been assessed by regulators
- Evaluate how evidence impacted the benefit-risk balance (e.g., which data are essential, which uncertainties are acceptable and which should be resolved, how are uncertainties expected to be resolved and when).
- Evaluate how this led to therapeutic indication-setting
- ...

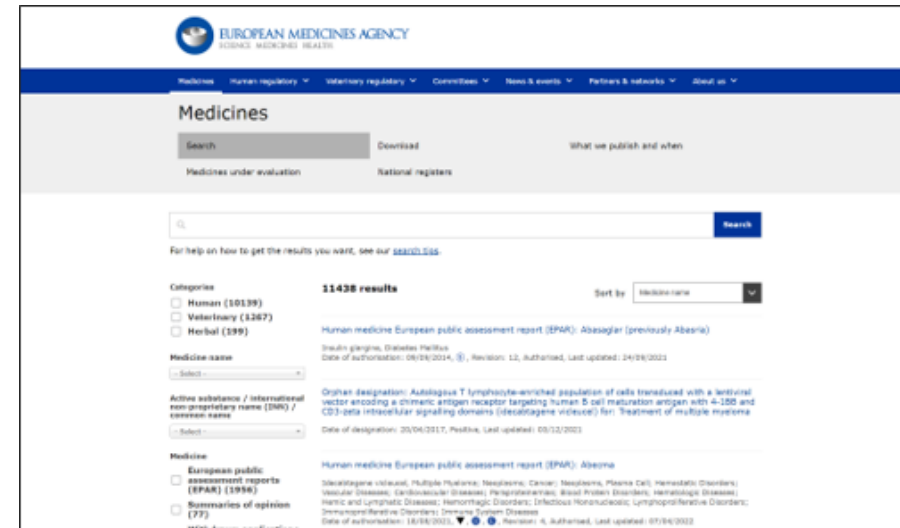
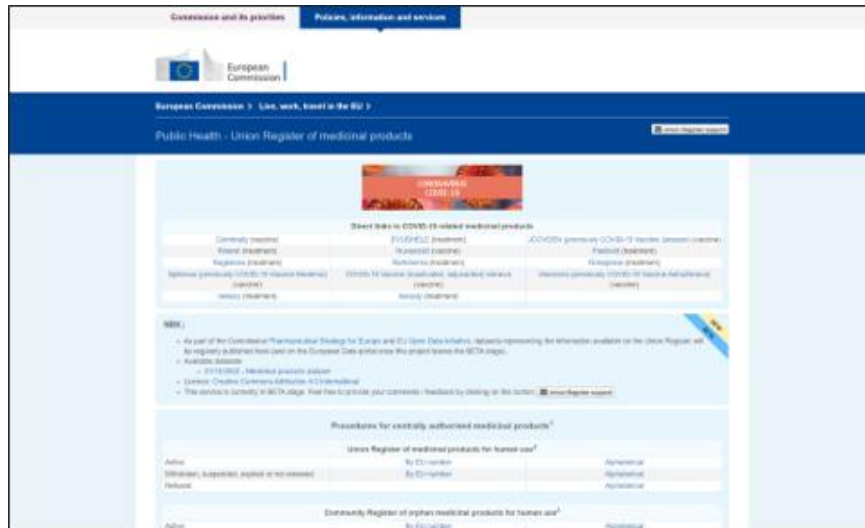
Data about, for example:

- ✓ Medicines assessed for marketing authorisation (largely public data)
- ✓ Medicines in development (confidential data, e.g., from scientific advice meetings)
- ✓ Tools and approaches in development (confidential data, e.g., from ITF meetings)



# EMRD: development of a 'data backbone'

Public data from, for example:













- European public assessment reports
- Summary of Product Characteristics
- Annexes to marketing authorisations that list additional studies to be performed
- Orphan drug designations
- Etcetera



# EMRD: development of a 'data backbone'

 By clicking on the  icon, it is possible to download all the linguistic versions of a specific Decision or Annex in a single package.



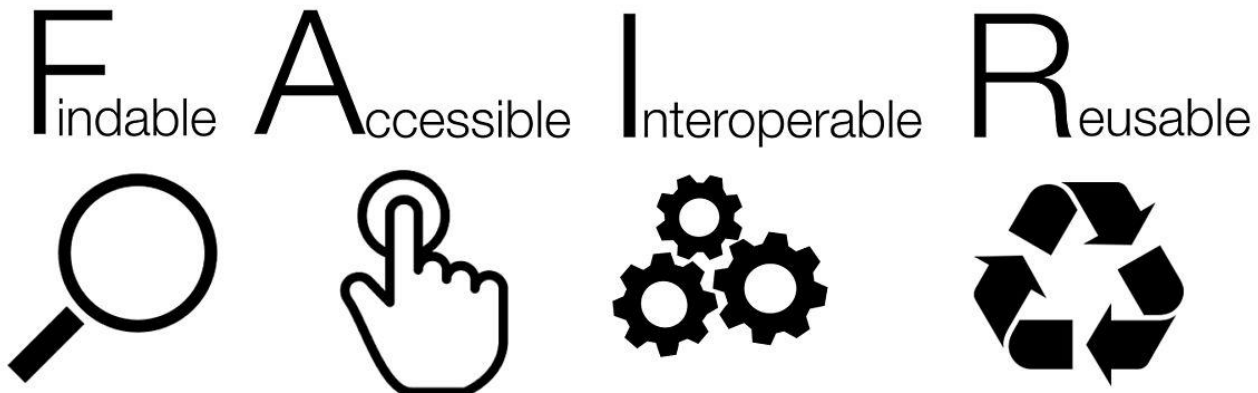
Close date	Procedure type	EMA number	Decision number	Summary	Decisions	Annexes
04 Jun 2019	Centralised - Authorisation	EMA/H/C/3691/	(2019) 4181 of 29 May 2019	- 	-  	-  
31 Oct 2019	Centralised - Variation	EMA/H/C/003691/IB/0003	-			
<b>Updated with:</b> Decision (2020) 2863 of 28 Apr 2020						
26 Mar 2020	Corrigendum	-	(2019) 4181 of 29 May 2019			-  
30 Apr 2020	Centralised - Annual renewal	EMA/H/C/003691/R/0005	(2020) 2863 of 28 Apr 2020	- 	-  	-  
08 Jul 2020	Centralised - Variation	EMA/H/C/003691/IB/0013	-			
<b>Updated with:</b> Decision (2021) 5248 of 09 Jul 2021						
01 Dec 2020	Centralised - Variation	EMA/H/C/003691/IAIN/0019/G	-			
<b>Updated with:</b> Decision (2021) 5248 of 09 Jul 2021						
18 Dec 2020	Centralised - Notification	EMA/H/C/003691/N/0020	-			

# European Medicines Regulatory Database

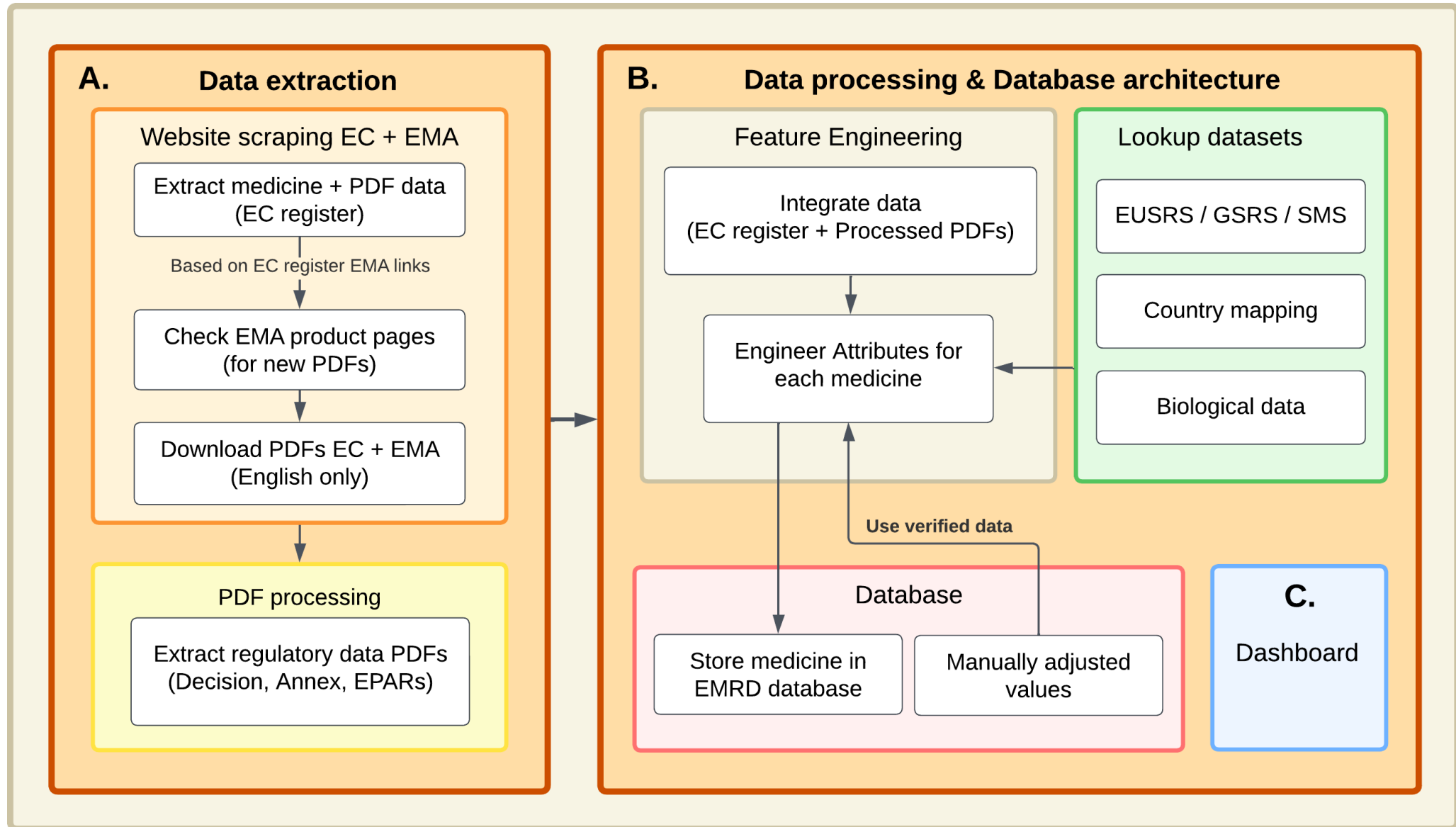
- ✓ Open data platform based on FAIR principles
- ✓ Users: regulatory science community, regulators, developers, patient organisations, etc.
- ✓ Initial scope: regulatory lifecycles of all medicines assessed by the EMA from 1995-to date

For example, on 19 May 2026:

- 1,965 authorised medicines
- Almost 70 variables: medicine, disease, legal and regulatory characteristics
- **>60,000 documents** (with much more data available)



# EMRD data workflow



Variable	Data source				
	EC Register	EC Decision	SmPC/Annex	EPAR	Other
<b>Medicinal product</b>					
Brand name (EU, current )	✓				
Brand name (EU, initial)		✓			
EMA application number	✓				
EU product number	✓				
Marketing authorisation holder (EU, current)	✓				
Marketing authorisation holder (EU, initial)		✓			
Therapeutic indication (EU, current)	✓				
Therapeutic indication(s) (EU, initial)			✓		
<b>Ingredients &amp; substances</b>					
Active substance (EU, current)	✓				
Active substance (EU, initial)		✓			
ATC code (EU, current) + levels 1-5	✓				
ATMP (EU)		✓			
New active substance (EU)		✓			
Substance type					Adapted GSRS / EUSRS
Substance type - subtype					Adapted GSRS / EUSRS
Substance synthesis method					Manual (SmPC)

Variable	Data source				
	EC Register	EC Decision	SmPC/Annex	EPAR	Other
<b>Marketing authorisation</b>					
Accelerated assessment (EU)				✓	
Authorisation status (EU, current)	✓				
Co-Rapporteur country (EMA)				✓	
Legal basis (EU)				✓	
Orphan designation (EU) at marketing authorisation	✓				
PRIME granted (EU)				✓	
Rapporteur country (EMA)				✓	
Re-examination performed (EMA)				✓	
Type of authorisation (EU, initial)		✓	✓		
<b>Marketing authorisation timeframe</b>					
Authorisation date (EU)	✓				
CHMP opinion date				✓	
Duration of assessment procedure (EU, total days)					Calculated
EMA assessment procedure start date				✓	



Search EMRD Database...



Search EMRD

## EU medicines overview

Based on data from the **EMRD**, this interactive chart offers insights into the **1965** EU medicines that have been authorised over the years.

**Authorisation Status**

Substance Types

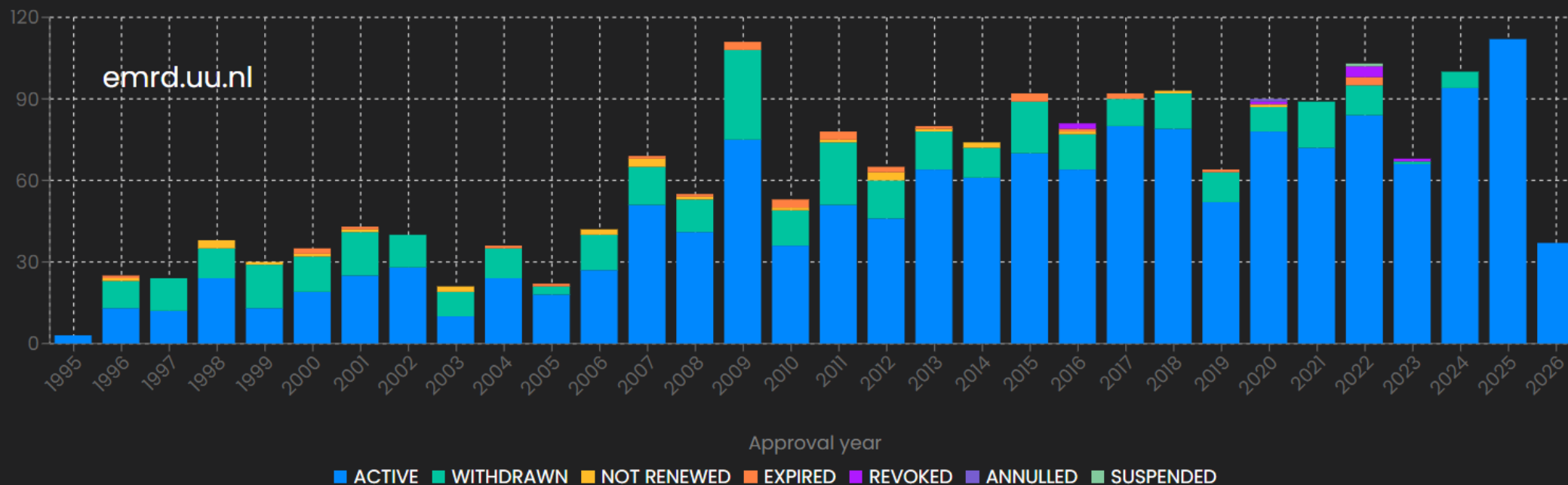
ATC Level 1

Legal Basis

Orphan Drugs


Authorisation Types

### Current Authorisation Status for EU approved medicines by Authorisation year






Search EMRD Database...

 Search EMRD

▼ Show selection


**Selected Medicines** - 1965 in selection


 Visualise Selection












 Export Selection

**Medicines** Last updated on 19 May 2026 - 1965 medicines available

 Sort

 Filter

 Export all shown

<input checked="" type="checkbox"/>	EU product number	Active substance (EU, current)	Brand name (EU, current)	Marketing authorisation holder	Authorisation date (EU)	
<input checked="" type="checkbox"/>	EU/1/26/2030	Insulin lispro	Bysumlog	Gan & Lee Pharmaceuticals Europe GmbH	6 May 2026	A 
<input checked="" type="checkbox"/>	EU/1/26/2017	mavorixafor	Xolremdi	X4 Pharmaceuticals (Austria) GmbH	27 April 2026	A 
<input checked="" type="checkbox"/>	EU/1/26/2022	tocilizumab	Tuyory	Gedeon Richter Plc.	27 April 2026	A 
<input checked="" type="checkbox"/>	EU/1/26/2026	levodopa/carbidopa	Onerji	Tanabe Pharma GmbH	27 April 2026	A 
<input checked="" type="checkbox"/>	EU/1/26/2031	teriparatide	Zandoriah	CINNAGEN CO, UNIPESSOAL LDA.	27 April 2026	A 
<input checked="" type="checkbox"/>	EU/1/25/2008	pertuzumab	Poherdy	N.V. Organon	23 April 2026	A 
<input checked="" type="checkbox"/>	EU/1/26/2021	paltusotine	Palsonify	Crinetics Pharmaceuticals Europe GmbH	23 April 2026	A 
<input checked="" type="checkbox"/>	EU/1/26/2023	etanercept	Fubelv	Biosimilar Collaborations Ireland Limited	23 April 2026	A 
<input checked="" type="checkbox"/>	EU/1/26/2024	remibrutinib	Rhapsido	Novartis Europharm Limited	23 April 2026	A 
<input checked="" type="checkbox"/>	EU/1/26/2025	tovorafenib	Ojemda	Ipsen Pharma	20 April 2026	A 
<input checked="" type="checkbox"/>	EU/1/26/2028	Influenza and COVID 19, mRNA vaccine	mCOMBRIAX	Moderna Biotech Spain S.L.	20 April 2026	A 





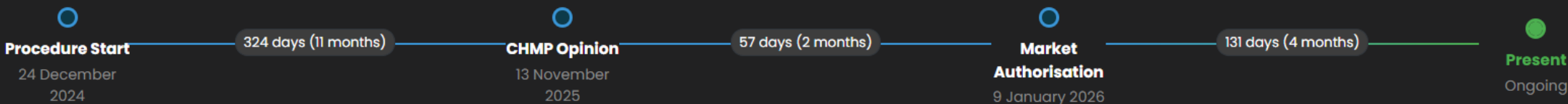
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## Waskyra

### Etuvetidigene autotemcel

**ATMP** **FULL APPLICATION** **ACTIVE**

Authorised by the EC on 9 January 2026



- [EC page](#)
- [EC Auth. SmPC](#)
- [EC Auth. decision](#)
- [EMA page](#)
- [EMA Auth. EPAR](#)

#### Therapeutic indication (EU, current)

Waskyra is indicated for the treatment of patients aged 6 months and older with Wiskott–Aldrich Syndrome (WAS) who have a mutation in the WAS gene for whom haematopoietic stem cell (HSC) transplantation is appropriate and no suitable human leukocyte antigen (HLA)-matched related haematopoietic stem cell donor is available.

#### Medicinal product

<b>Brand name (EU, current)</b> ?	Waskyra
<b>Brand name (EU, initial)</b> ?	Waskyra
<b>EMA application number</b> ?	EMEA/H/C/006525 <a href="#">(Visit EMA medicine page)</a>
<b>EU product number</b> ?	EU/1/25/1996 <a href="#">(Visit EC medicine page)</a>



# EMRD: not just a database...

**European Medicines Regulatory Database**

**DocShark**

Search and explore regulatory documents

"targeted therapy" AND ("breast cancer" OR "ovarian cancer")

Search

Guide

**Choose scope:**  
Which medicines to search documents for?

All medicines  EMRD selection (31 medicines)

**Select document type(s):**  
Which documents to search through?

Auth. EPAR  EC Auth. Annex (Incl. SmPC)  EC Auth. Decision

# Summary

- European Medicines Regulatory Database: a real-time, web-based, open access platform
- All medicines authorised by the European Commission since 1995
- Improves findability of regulatory data sources
- Centralises structured and validated regulatory data
- Enables querying underlying unstructured regulatory data sources
- Next steps:
  - Publish supporting manuscript
  - Launch the EMRD v1.0 (fully open)

# Questions?

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