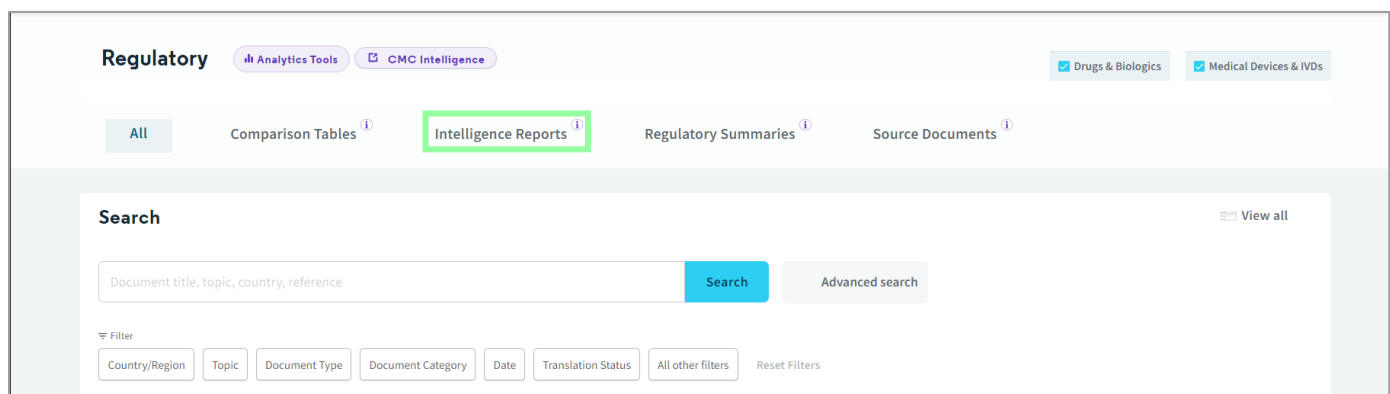


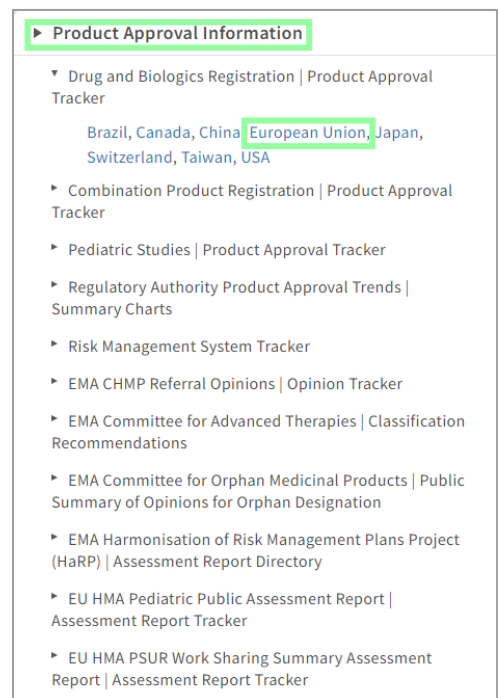
# Maximizing EU Approval Tracker

Do you need to compare existing and emerging competitor products approved in the European Union? Do you want to find out which products were approved in your field of interest? With Cortellis Regulatory Intelligence you can quickly locate a list of EU centralized products compiled into a single Excel table.

1. On the Cortellis Regulatory home page click **Intelligence Reports** tab and scroll down to **Product Approval Information**.



2. Expand **Product Approval Information** and click on **European Union**.



3. The **Abstract** under the **Summary** provides information on the scope of the document, when it was last updated and more.

Valid

154019

European Union

Regulatory Intelligence Report

Approval Tracker

Drugs and Biologics

Product Assessment

1. Summary

2. Document

3. Reason For Update

4. Mentioned Documents

5. Mentioned By

Summary

Abstract

This Regulatory Intelligence Report (RIR) provides a list of all centralized products approved since their first EPAR, and products withdrawn and suspended since 01-Mar-2012. In addition, this RIR provides all the revisions of EPARs published by the EMA. It allows a search for general information on each medicinal product, the registration process and some product regulatory information. The product type classification as "Product Type" and the main therapeutic area have been assigned and are not provided by the CHMP. The "Medical Device Component" column differentiates between products that possess, or not, a medical device component. The "Application/Submission Type" column provides information on the Article used by the applicant to submit the medicinal product application. Information is extracted from the EPAR on regulatory information such as Active substance status\*, Review Type, whether the product was approved under Conditional approval or Exceptional circumstances. A Detailed status for fixed dose combination is also provided\*\*. Registration status is clearly shown for each product. Products are identified as orphan, PRIME and/or ATMP, along with the corresponding designation date. For withdrawn and suspended products, information is provided with regards to the reason for withdrawal/suspension. The withdrawal/suspension date is also indicated. In the "Pediatric Usec column: a "Yes" is mentioned if the pediatric use is stated in the product information approved (either in section Posology and method of administration - pediatric population, indication or any other section), otherwise a "No" is mentioned. The column "EMA Revision Rationale" provides a detailed description of the major and minor changes introduced by each revision. The column "EMA Revision Type" classifies these changes into categories. This includes changes in manufacturing, patient population, therapeutic indication(s), and formulation.

\*The active substance status is explicitly included in EPARs since Jun-2011: known active substance or new active substance status is given from this date. For previous marketing authorizations delivered, active substance status is considered as Not available. For generic medicinal products after Jun-2011 Active Substance Status is Known.

\*\*Detailed status is considered as Not available if EPAR dates before Jun-2011.(<)

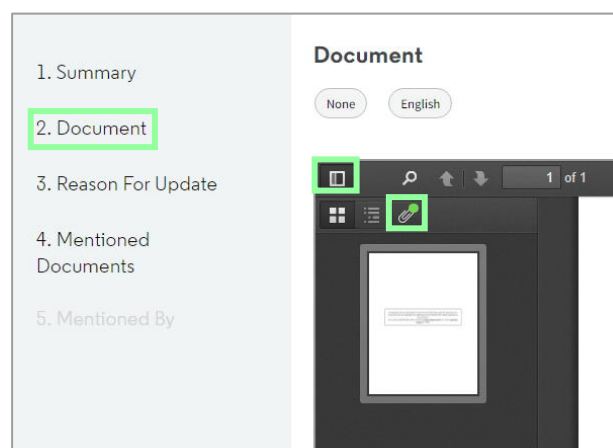
Last Updated Date

31-Aug-2023

Added Date

04-Jan-2013

4. To open the Excel version of the document for easy sorting and filtering, click **“Download Excel”** button, or click **Document**, then the **Toggle Side Bar icon** in the upper left-hand corner of the PDF. Click the **Paperclip icon** that appears to open the attached Excel spreadsheet.



- In the Excel table you'll find the products categorized by Product Name, Therapeutic Area, Product and Review Type, Registration Status and Dates, Company and other information, such as Rapporteur/Co-Rapporteur Names and Countries. Sort and Filter the table as desired.

	A	B	C	D
1	Link to Product Approval Document	Active Ingredient(s)	Name	Application Number
2	<a href="#">371358</a>	rituximab	RIXATHON	EMA/H/C/003903 Rev. 11
3	<a href="#">371343</a>	albutrepenonacog alfa	IDELVION	EMA/H/C/003955 Rev. 12
4	<a href="#">371334</a>	macimorelin	GHRVELIN ; MACIMORELIN AETERNA ZENTARIS	EMA/H/C/004660 Rev. 3
5	<a href="#">371331</a>	chenodeoxycholic acid	CHENODEOXYCHOLIC ACID LEADIANT ; CHENODEOXYCHOLIC ACID SIGMA-TAU	EMA/H/C/004061 Rev. 6
6	<a href="#">371330</a>	filgrastim	ZARZIO	EMA/H/C/000917 Rev. 23

- Click on the **Link to Product Approval Document** (column A) for direct access to the initial EPAR version and revisions.



EMA/327914/2021  
EMA/H/C/003903

## Rixathon (*rituximab*)

An overview of Rixathon and why it is authorised in the EU

### What is Rixathon and what is it used for?

Rixathon is a medicine used to treat the following blood cancers and inflammatory conditions:

- follicular lymphoma and diffuse large B cell non-Hodgkin's lymphoma (two types of non-Hodgkin's lymphoma, a blood cancer);
- chronic lymphocytic leukaemia (CLL, another blood cancer affecting white blood cells);
- severe rheumatoid arthritis (an inflammatory condition of the joints);
- granulomatosis with polyangiitis (GPA or Wegener's granulomatosis) and microscopic polyangiitis (MPA), which are inflammatory conditions of the blood vessels;

For more information contact Customer Service at **LS Product Support**.