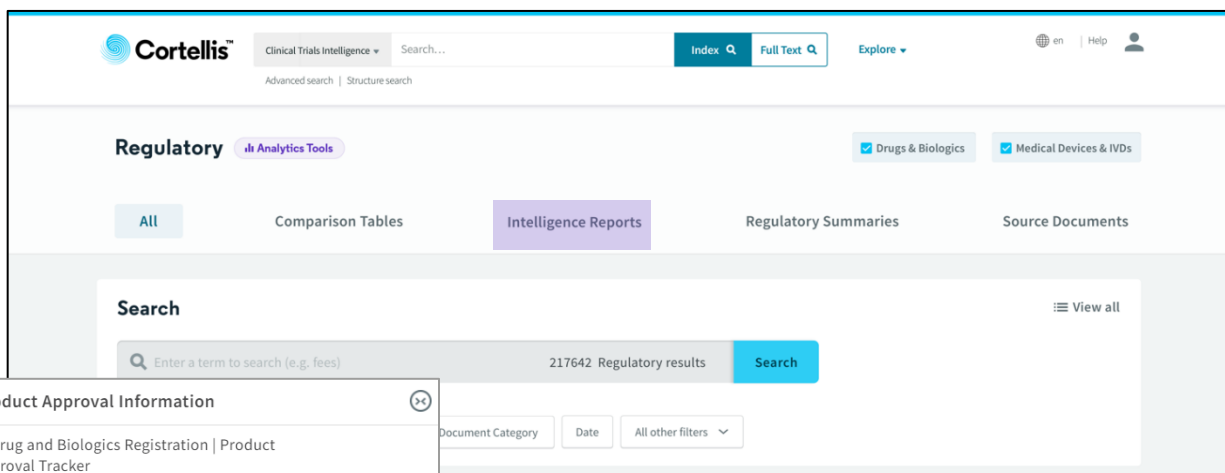


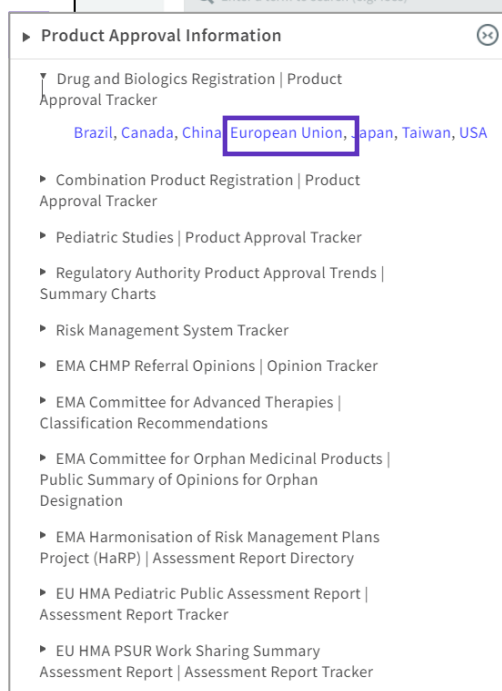
Maximizing the EU Approval Tracker

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** and scroll down to **Product Approval Information**.



2. Expand **Drug Submission and Approval Overview** and click on **European Union**.



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

EU Medicinal Products Registration Overview

Valid 154019 European Union Regulatory Intelligence Report Approval Tracker

Drugs and Biologics Product Assessment

1. Summary
2. Document
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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Intelligence Report (RIR) provides a list of all centralized products approved since their first EPAR and products withdrawn and suspended since 01-Mar-2012.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 revision of EPARs published by the EMA since Sep-2019. 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. In the "Pediatric Use" column: a "Yes" is mentioned if pediatric data are available for the active substance. When no pediatric data are available or pediatric data are available but for another salt or for a fixed combination, a "No" is mentioned.

*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-2011.¹

Reason for Update
This is updated to include any new and updated content related to the EU Medicinal Products Registration Overview Intelligence Report

Date
26-Nov-2020

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

1. Summary
2. Document
3. Mentioned By

Document

None English

Download Excel Expand

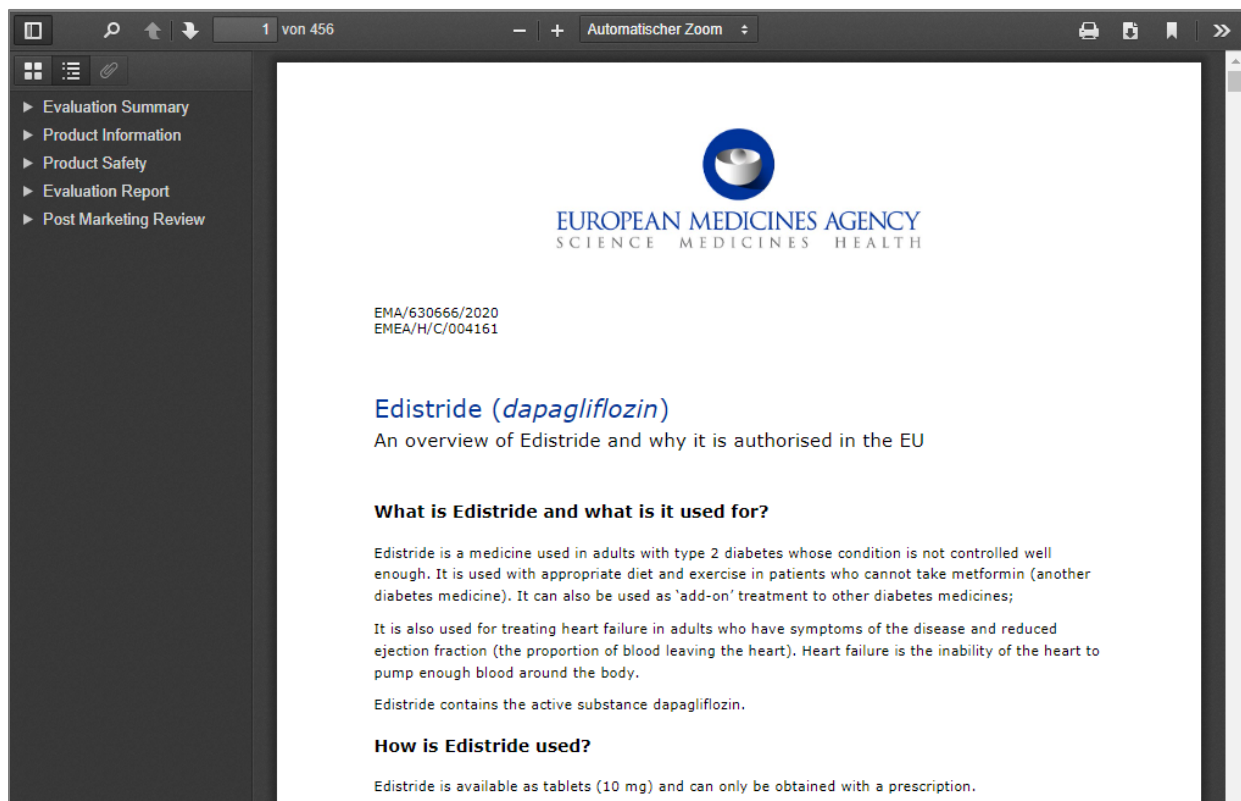
1 von 1

xlsx-report-154019.xlsx

- 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	E	F	G	H	
1	Link to Product Approval Document	Active Ingredient(s)	Name	Application Number	Therapeutic Area	Indication(s)	Dosage Form	Route of Administration	Pharmaceu
	321589	quadrivalent influenza vaccine (recombinant, prepared in cell culture)	SUPEMTEK	EMA/H/C/005159	Infections	- SUPEMTEK is indicated for active immunization for the prevention of influenza disease in adults. - SUPEMTEK should be used in accordance with official	Solution	Intramuscular	One dose (0. haemagglutins: A/XX A/XXXXX (H micrograms
2	321586	dapagliflozin	EDISTRIDE	EMA/H/C/004161 Rev 14	Endocrine disorders	- EDISTRIDE is indicated in adults for the treatment of insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise - as monotherapy when metformin is considered inappropriate due to intolerance. - In addition to other medicinal	Tablet	Oral	5 mg; 10 mg
3	321585	nivolumab	OPDIVO	EMA/H/C/003985 Rev.33	Cancer	- OPDIVO is indicated for: - Melanoma: - OPDIVO as monotherapy or in combination with ipilimumab is	Solution	Intravenous	10 mg/ml

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



EMA/630666/2020
EMA/H/C/004161

Edistride (*dapagliflozin*)

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

What is Edistride and what is it used for?

Edistride is a medicine used in adults with type 2 diabetes whose condition is not controlled well enough. It is used with appropriate diet and exercise in patients who cannot take metformin (another diabetes medicine). It can also be used as 'add-on' treatment to other diabetes medicines;

It is also used for treating heart failure in adults who have symptoms of the disease and reduced ejection fraction (the proportion of blood leaving the heart). Heart failure is the inability of the heart to pump enough blood around the body.

Edistride contains the active substance dapagliflozin.

How is Edistride used?

Edistride is available as tablets (10 mg) and can only be obtained with a prescription.

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