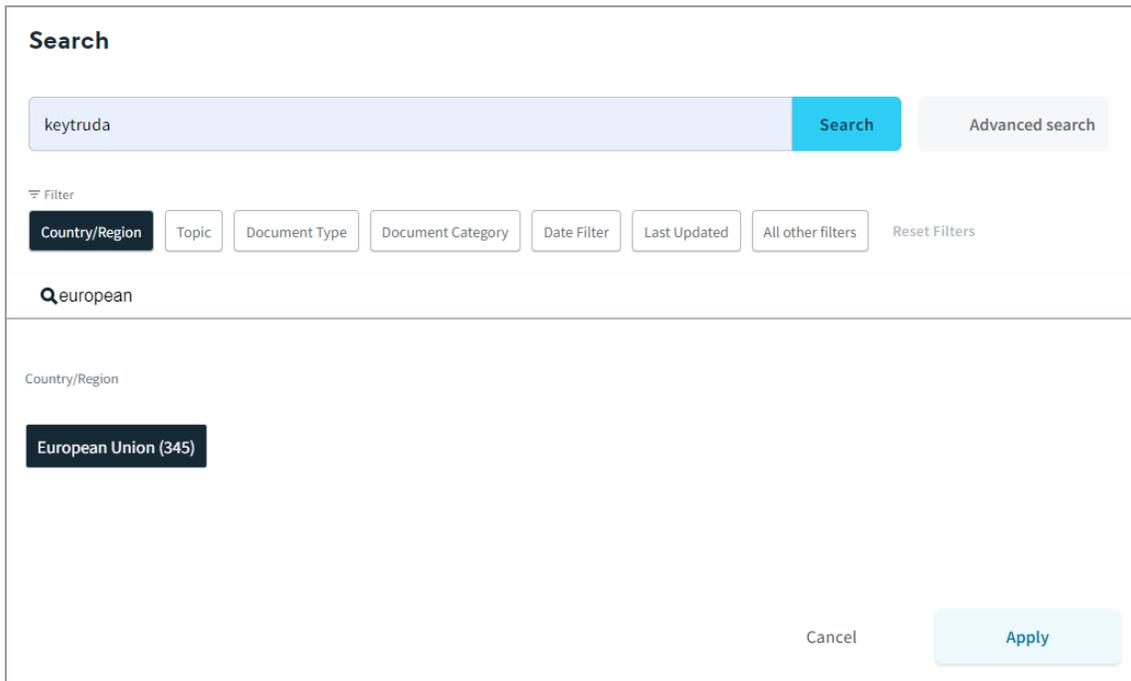


# Cortellis Regulatory Intelligence

## European Public Assessment Reports (EPARs)

This guide shows you how to quickly access and fully benefit from the European Public Assessment Reports (EPARs) in *Cortellis Regulatory Intelligence*, which covers all current and outdated versions since the beginning of the centralized procedure in 1995.

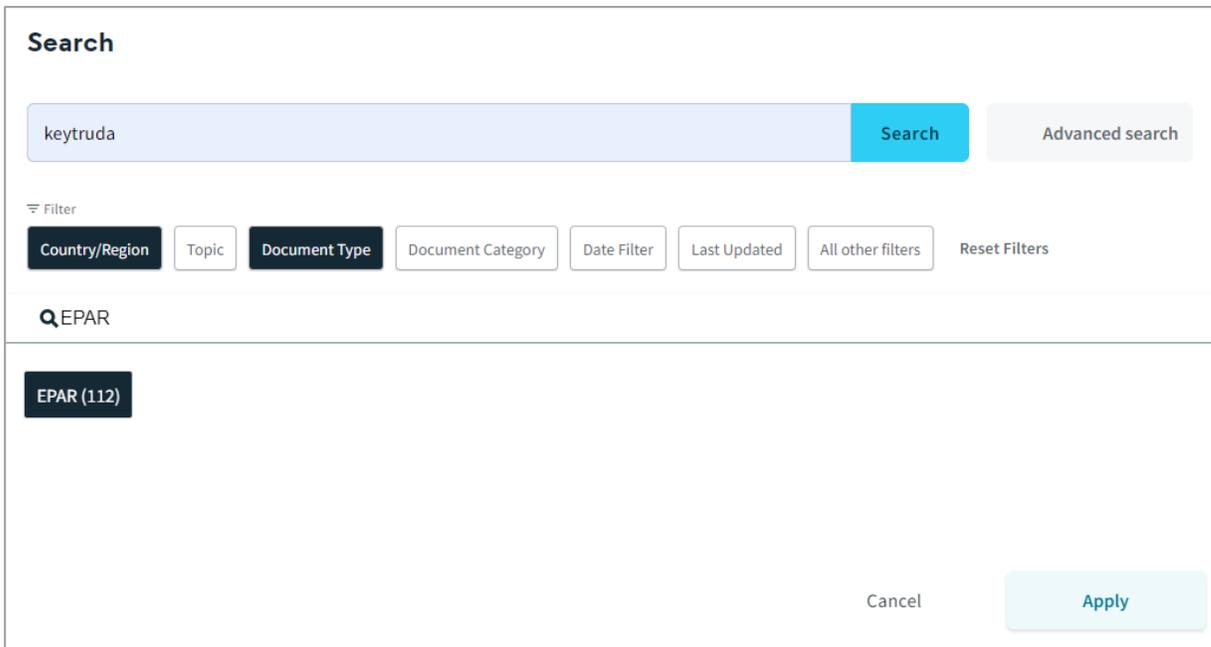
1. Use the Search Tool from the Regulatory Home Page. Type Keytruda into the Search Bar. Then select the **Country/Region** Tab and click on **European Union**. Then click **Apply**. Once you've applied a filter to a tab it turns black.



The screenshot shows the search interface with the following elements:

- Search Bar:** Contains the text "keytruda". To the right are buttons for "Search" and "Advanced search".
- Filter Section:** Labeled "Filter" with a dropdown arrow. It contains several filter tabs: "Country/Region" (which is highlighted in black), "Topic", "Document Type", "Document Category", "Date Filter", "Last Updated", and "All other filters". A "Reset Filters" link is also present.
- Search Results:** A search bar contains the text "european". Below it, under the heading "Country/Region", a single filter option "European Union (345)" is displayed in a black box.
- Buttons:** At the bottom right, there are "Cancel" and "Apply" buttons.

- Next Select **Document Type** and **EPAR**. Again click Apply. Select **Document Category** in the same way. Choose **Reference Document**.



**Search**

keytruda Search Advanced search

Filter

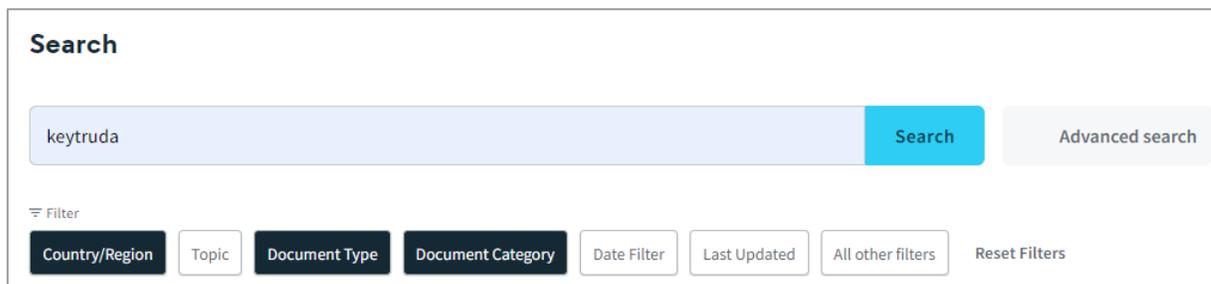
**Country/Region** Topic **Document Type** Document Category Date Filter Last Updated All other filters Reset Filters

Q EPAR

**EPAR (112)**

Cancel Apply

- Once your search is complete click the blue **Search** button.



**Search**

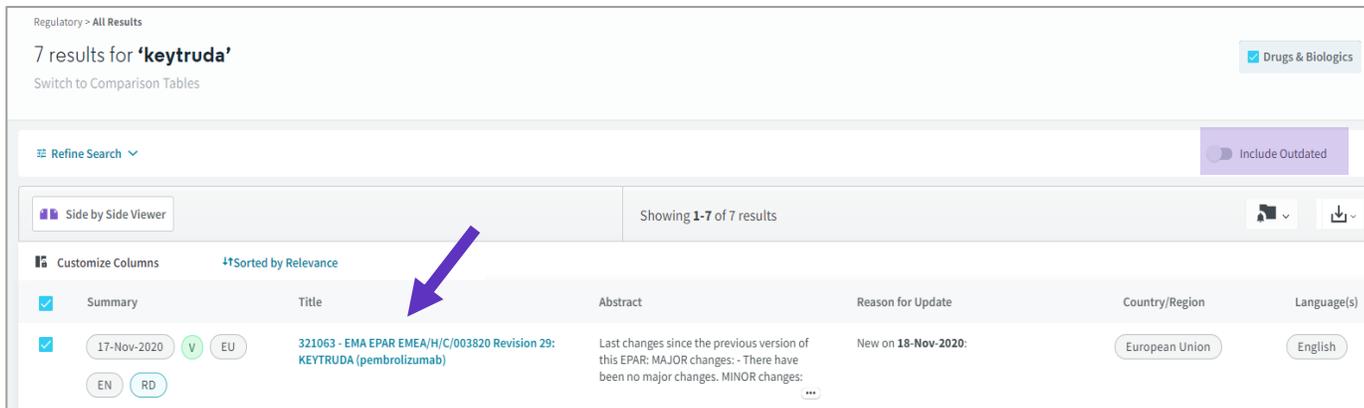
keytruda Search Advanced search

Filter

**Country/Region** Topic **Document Type** **Document Category** Date Filter Last Updated All other filters Reset Filters

- Once the results page is displayed, click the **blue title hyperlinks** to view the EPAR documents. The valid EPAR version of the product requested appears at the top of the list. Other products' EPARs might be listed if the product name requested is mentioned in those documents.

Tip: Toggle on **Include Outdated** to include previous EPAR versions in the results list.



Regulatory > All Results  
7 results for 'keytruda'  
Switch to Comparison Tables

Drugs & Biologics

Refine Search

Include Outdated

Side by Side Viewer

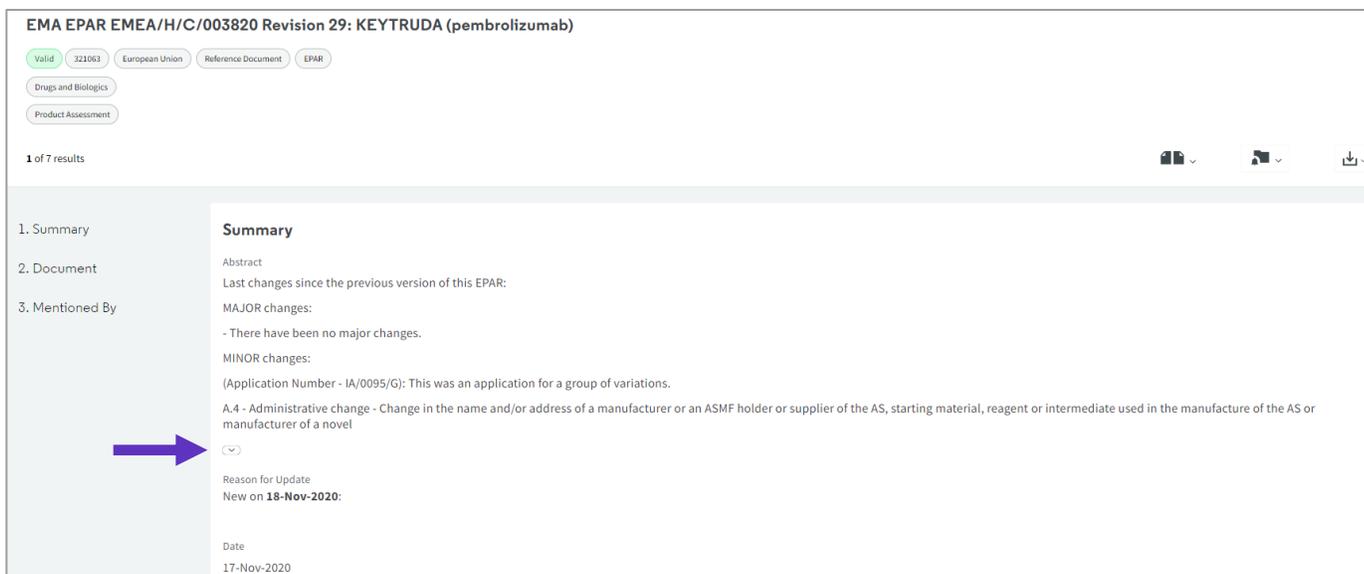
Showing 1-7 of 7 results

Customize Columns

Sorted by Relevance

Summary	Title	Abstract	Reason for Update	Country/Region	Language(s)
<input checked="" type="checkbox"/> 17-Nov-2020 <input checked="" type="checkbox"/> EU <input type="checkbox"/> EN <input type="checkbox"/> RD	<a href="#">321063 - EMA EPAR EMEA/H/C/003820 Revision 29: KEYTRUDA (pembrolizumab)</a>	Last changes since the previous version of this EPAR: MAJOR changes: - There have been no major changes. MINOR changes:	New on <b>18-Nov-2020</b> :	<input type="text" value="European Union"/>	<input type="text" value="English"/>

- On the document page the **Summary** section will be displayed that includes a value-added **Abstract** written by Cortellis experts. This provides key data on the product, such as indication, pharmaceutical form, administration routes and packaging. Each abstract highlights the major and minor changes compared to the previous version. If the product is an orphan drug, has a pediatric indication or if a Risk Management Plan is in place, the abstract also provides this information. Click the **arrow** to expand or collapse the abstract text.



EMA EPAR EMEA/H/C/003820 Revision 29: KEYTRUDA (pembrolizumab)

Valid 321063 European Union Reference Document EPAR

Drugs and Biologics

Product Assessment

1 of 7 results

1. Summary

2. Document

3. Mentioned By

**Summary**

Abstract

Last changes since the previous version of this EPAR:

MAJOR changes:

- There have been no major changes.

MINOR changes:

(Application Number - IA/0095/G): This was an application for a group of variations.

A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel

Reason for Update

New on **18-Nov-2020**:

Date

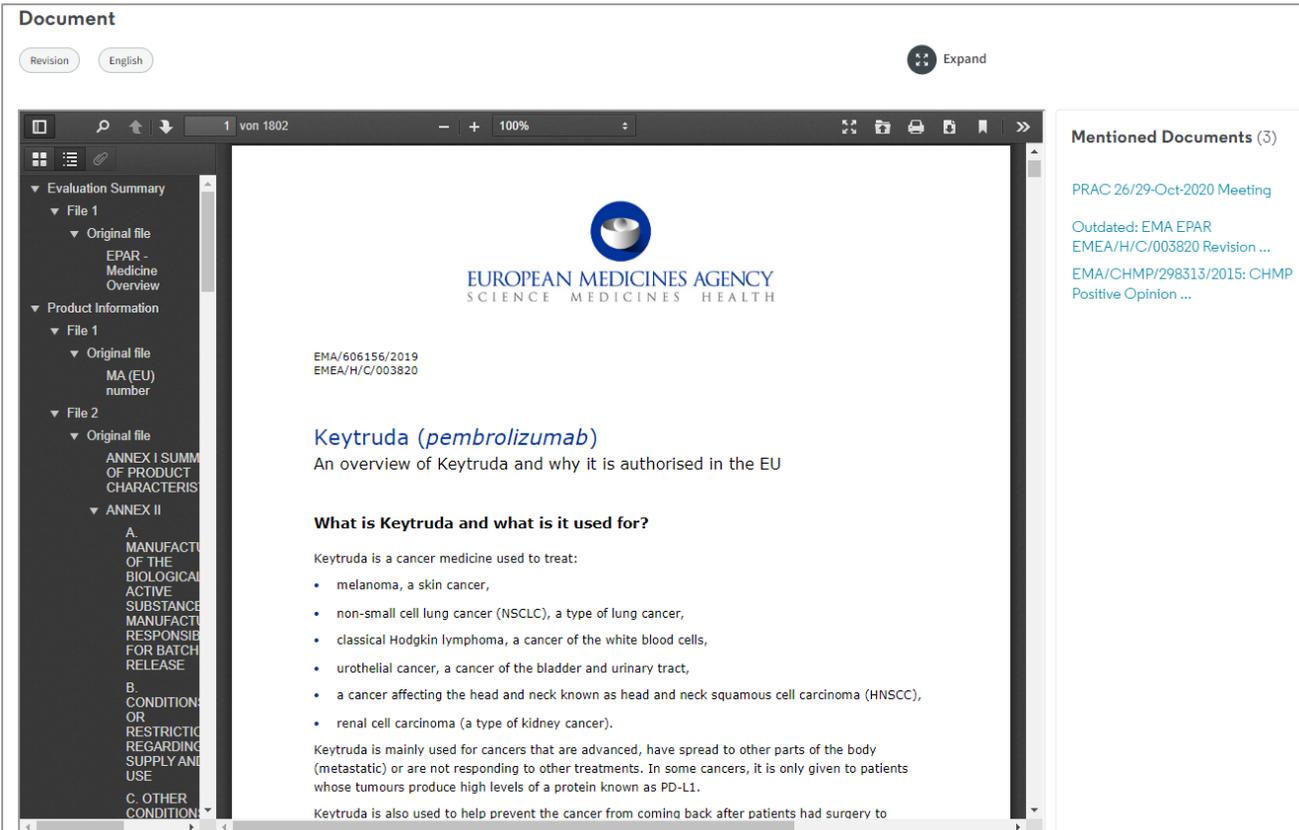
17-Nov-2020

Tip: If an earlier version exists, you can link to it in the Abstract and information on the previous version including the EMA reference, revision and hyperlinked IDRAC number are provided. Previous versions are identified by a red **Outdated** stamp.

This is a current version which outdates EMEA/H/C/003820 Revision 28: KEYTRUDA (pembrolizumab). (IDRAC 316991)

NB: This exclusive document has been prepared integrating the files released in English by the EMA into one comprehensive document. Consequently, the page numbering is not in sequence, but has been left so that the user can appreciate the reorganisation. It is also enriched by a detailed Table of Contents provided in the left frame

- On the document page, scroll down to access the **full EPAR document**. In Cortellis all files released in English by the EMA relating to a specific version are compiled into one single PDF file. Documents are fully searchable and include the product information comprising the summary of product characteristics, labelling, package leaflet as well as the scientific evaluation, discussion and conclusion. EPARS are also enriched by a hyperlinked table of contents provided on the left, which allows you to directly go to the sections of interest (depending on your browser, you may need to click the table of contents symbol first or download the PDF first in order to see the details on the left). From **Mentioned Documents** you can link out to other documents cited by the EPAR.



**Document**

Revision English Expand

1 von 1802 100%

- ▼ Evaluation Summary
  - ▼ File 1
    - ▼ Original file
      - EPAR - Medicine Overview
  - ▼ Product Information
    - ▼ File 1
      - ▼ Original file
        - MA (EU) number
      - ▼ File 2
        - ▼ Original file
          - ANNEX I SUMMARY OF PRODUCT CHARACTERISTICS
          - ▼ ANNEX II
            - A. MANUFACTURE OF THE BIOLOGICAL ACTIVE SUBSTANCE MANUFACTURE RESPONSIBLE FOR BATCH RELEASE
            - B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE
            - C. OTHER CONDITIONS

  
**EUROPEAN MEDICINES AGENCY**  
 SCIENCE MEDICINES HEALTH

EMA/606156/2019  
EMEA/H/C/003820

**Keytruda (pembrolizumab)**  
An overview of Keytruda and why it is authorised in the EU

**What is Keytruda and what is it used for?**

Keytruda is a cancer medicine used to treat:

- melanoma, a skin cancer,
- non-small cell lung cancer (NSCLC), a type of lung cancer,
- classical Hodgkin lymphoma, a cancer of the white blood cells,
- urothelial cancer, a cancer of the bladder and urinary tract,
- a cancer affecting the head and neck known as head and neck squamous cell carcinoma (HNSCC),
- renal cell carcinoma (a type of kidney cancer).

Keytruda is mainly used for cancers that are advanced, have spread to other parts of the body (metastatic) or are not responding to other treatments. In some cancers, it is only given to patients whose tumours produce high levels of a protein known as PD-L1.

Keytruda is also used to help prevent the cancer from coming back after patients had surgery to

**Mentioned Documents (3)**

- PRAC 26/29-Oct-2020 Meeting
- Outdated: EMA EPAR EMEA/H/C/003820 Revision ...
- EMA/CHMP/298313/2015: CHMP Positive Opinion ...

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