

Optimizing Cortellis for labeling policy & strategy

Agenda

30 mins + 15 mins Q&A

- Introduction
- Live demo
- Follow-up and Q&A

What is Cortellis Regulatory Intelligence?

Global regulatory information, across all functions and responsibilities



290K+ official documents



8K+ value-add regulatory reports, analyses and global comparisons



All documents translated to English



**81 countries and regions
Drugs & Biologic and
75 Medical Devices & IVDs**







Updated daily



Regulatory experts & local consultants

Scenario

I am responsible for labeling policy/strategy, and I need to:

-  1. Track US and EU labels by drug, disease, regulatory designation and more
-  2. Compare packaging and labeling requirements across multiple countries; for example, are Mandatory Warnings or Braille language required?
-  3. Discover curated reports providing the guidance I need on labeling policy plus link to source documents and English translations
-  4. Understand the competition - find approved drugs for thousands of indications globally



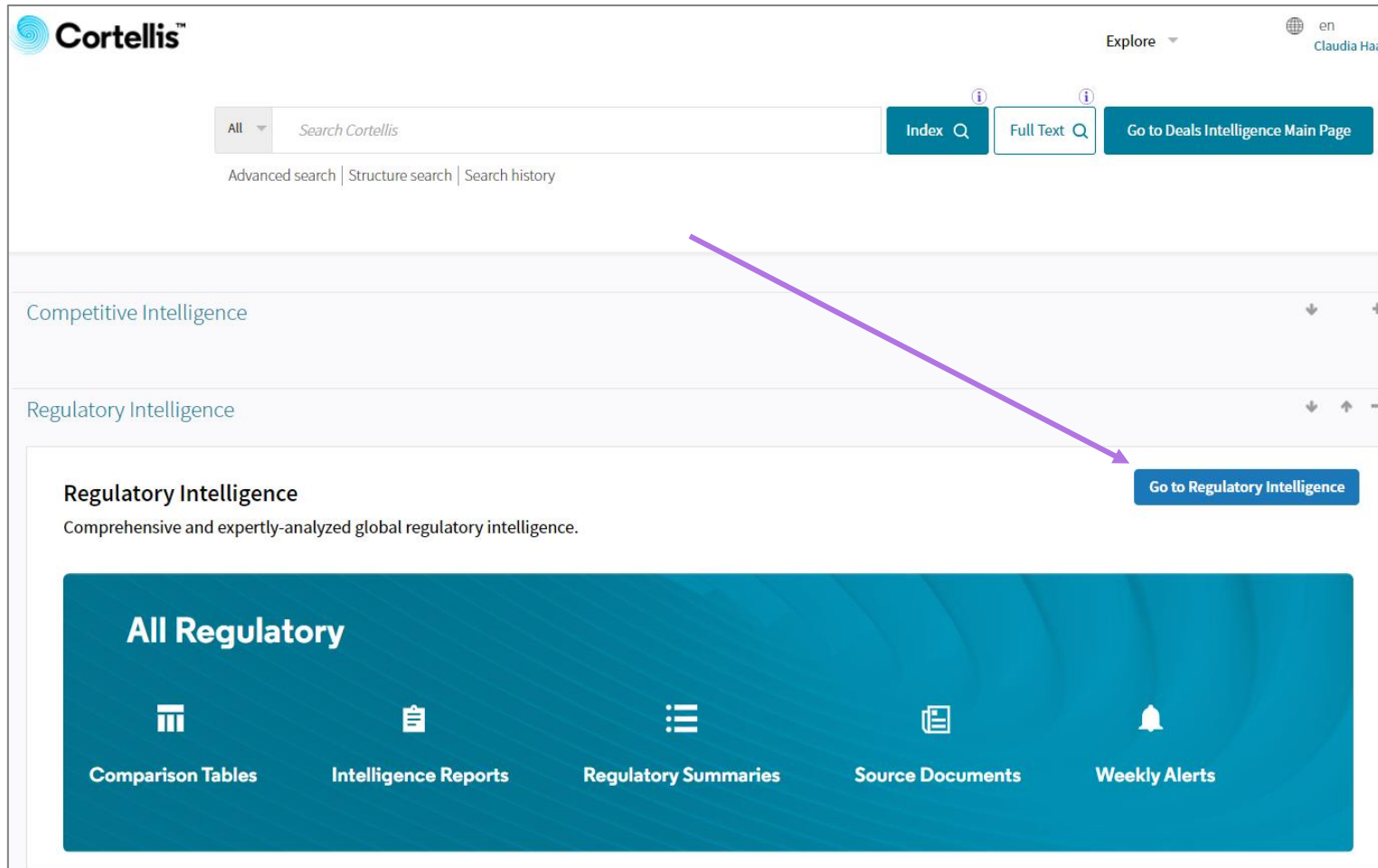
Cortellis label coverage

Cortellis contains US and EU Labels because the FDA and EMA publish labels within their approval packages

- Approvals documents for these countries are also in Cortellis:
 - China, Japan, Singapore, Taiwan, Switzerland, Brazil, Canada and coming soon, UK
- Since labels are not included in these countries' approval documents, they are not included in Cortellis

Cortellis Landing Page

Click the “**Go to...**” button to access Cortellis Regulatory Intelligence



Cortellis Regulatory Homepage

Start searching through all documents, click the tabs to browse value-add tables, reports and summaries or access the Cortellis Weekly Alerts newsletter.

The screenshot displays the Cortellis Regulatory homepage. On the left is a dark sidebar with icons for home, navigation, documents, filters, and reports. The main content area has a top navigation bar with 'Regulatory' and tabs for 'Analytics Tools' and 'CMC Intelligence'. A 'Drugs & Biologics' filter is active. Below this is a tabbed interface with 'All', 'Comparison Tables', 'Intelligence Reports', 'Regulatory Summaries', and 'Source Documents'. The 'All' tab is selected. The central section features a 'Search' bar with a placeholder 'Document title, topic, country, reference' and a 'Search' button, alongside an 'Advanced search' link. Below the search bar are filter buttons for 'Country/Region', 'Topic', 'Document Type', 'Document Category', 'Date', 'Translation Status', and 'All other filters', along with a 'Reset Filters' button. The bottom left contains 'Ask the Expert' and 'Local Consultants' sections. The bottom right features a 'Weekly Alerts' section for 'Drugs & Biologics', showing three alert cards: '2023 Volume 47' (Current Issue), '2023 Volume 46' (06-Nov-2023 to 10-Nov-2023), and '2023 Volume 45' (30-Oct-2023 to 03-Nov-2023).

Regulatory **Analytics Tools** **CMC Intelligence** ☒ Drugs & Biologics

All Comparison Tables Intelligence Reports Regulatory Summaries Source Documents

Search

Document title, topic, country, reference **Search** Advanced search

Filter

Country/Region Topic Document Type Document Category Date Translation Status All other filters Reset Filters

Ask the Expert

Local Consultants

Weekly Alerts

Drugs & Biologics

2023 Volume 47 **Current Issue**

2023 Volume 46
06-Nov-2023 to 10-Nov-2023

2023 Volume 45
30-Oct-2023 to 03-Nov-2023

Find US and EU labels by drug, disease, regulatory designation and more

Quick Search – drug name

The screenshot displays the Clarivate Regulatory Quick Search interface. The search bar contains the text "Breyanzi". The "Search" button is highlighted. Below the search bar, the "Filter" section is visible, with "Document Type" selected. The "Document Type" filter shows a list of options: Guideline (5), Notification (5), Press Release (5), Supplemental Approval - BLA (5), EPAR (4), CHMP opinion (2), Evaluation Report (2), Meeting (2), Product Approval (2), Product Miscellaneous (2), Newsletter (1), Original Approval - BLA (1), Product Approval Bulletin (1), Product Information (1), Speech (1), and Summary Basis Of Decision (1). The "Apply" button is highlighted.

Find US and EU labels for Breyanzi.

1. Go to Quick Search on the Home Page

2. Type BRYANZI into the keyword search box

3. Select Document type filter and select the approval documents.

Breyanzi is a biologic so for the US select Original Approval – BLA and Supplemental Approval – BLA and for the EU, EPAR.

For small molecules in the USA choose Supplemental Approval – NDA and Original Approval – NDA

5. Click Apply and click Search

Find US and EU labels by drug, disease, regulatory designation and more

Quick Search – drug name

1. Click the title to open the document
2. Select Document
3. Click Labeling in the table of contents

Customize Columns	Sorted by Relevance			
Summary		Title		Abstract
<input checked="" type="checkbox"/>	05-Feb-2021 V US EN RD	Biologics License Application (BLA) 125714: BREYANZI (lisocabtagene maraleucel) Suspension for Injection – Approval Package, 05-Feb-2021		On February 05, 2021, FDA approved biologics license application BLA 125714 for BREYANZI (lisocabtagene maraleucel). It
<input checked="" type="checkbox"/>	28-Dec-2023 V EU EN RD	EMA EPAR EMEA/H/C/004731 Revision 3: BREYANZI (lisocabtagene maraleucel)		Last changes since the previous version of
<input checked="" type="checkbox"/>	24-Jun-2022 V US EN RD	Biologics License Application 125714/090: BREYANZI (lisocabtagene maraleucel) Suspension for Injection – Approval Package, 24-Jun-2022		
<input checked="" type="checkbox"/>	14-Mar-2024 V US EN RD	Biologics License Application 125714/205: BREYANZI (lisocabtagene maraleucel) Suspension for Injection – Approval Package, 14-Mar-2024		

1. Summary
2. Snapshot
3. Document
4. Reason For Update
5. Mentioned Documents
6. Mentioned By

448 of 553

Automatic Zoom

▼ Evaluation Decision

File 1

Original file

APPROVAL LETTER

► Evaluation Summary

▼ Product Information

File 1

Original file

▼ LABELING

HIGHLIGHTS OF PRESCRIBING INFORMATION

FULL PRESCRIBING INFORMATION: CONTENTS*

▼ FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

2 DOSAGE AND ADMINISTRATION

2.1 Dose

2.2 Administration

2.3 Management of

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use BREYANZI safely and effectively. See full prescribing information for BREYANZI.

BREYANZI® (lisocabtagene maraleucel) suspension for intravenous infusion

Initial U.S. Approval: 2021

WARNING: CYTOKINE RELEASE SYNDROME and NEUROLOGIC TOXICITIES

See full prescribing information for complete boxed warning.

- Cytokine Release Syndrome (CRS), including fatal or life-threatening reactions, occurred in patients receiving BREYANZI. Do not administer BREYANZI to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab with or without corticosteroids (2.2, 2.3, 5.1).
- Neurologic toxicities, including fatal or life-threatening reactions, occurred in patients receiving BREYANZI including concurrently with CRS, after CRS resolution, or in the absence of CRS. Monitor for neurologic events after treatment with BREYANZI. Provide supportive care and/or corticosteroids as needed (2.2, 2.3, 5.2).
- BREYANZI is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the BREYANZI REMS (5.5).

INDICATIONS AND USAGE

BREYANZI is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular

DOSAGE FORMS AND STRENGTHS

- BREYANZI is a cell suspension for infusion (3).
- A single dose of BREYANZI contains 50 to 110 × 10⁶ CAR-positive viable T cells (consisting of 1:1 CAR-positive viable T cells of the CD8 and CD4 components), with each component supplied separately in one to four single-dose 5 mL vials (3). Each mL contains 1.5 × 10⁶ to 70 × 10⁶ CAR-positive viable T cells (3).

CONTRAINDICATIONS

None (4).

WARNINGS AND PRECAUTIONS

- Hypersensitivity Reactions: Monitor for hypersensitivity reactions during infusion (5.4).
- Serious Infections: Monitor patients for signs and symptoms of infection; treat appropriately (5.5).
- Prolonged Cytopenias: Patients may exhibit Grade 3 or higher cytopenias for several weeks following BREYANZI infusion. Monitor complete blood counts (5.6).
- Hypogammaglobulinemia: Monitor and consider immunoglobulin replacement therapy (5.7).
- Secondary Malignancies: In the event that a secondary malignancy occurs after treatment with BREYANZI, contact Bristol-Myers Squibb at 1-888-805-4355 (5.8).
- Effects on Ability to Drive and Use Machines: Advise patients to refrain from driving and engaging in hazardous occupations or activities, such as operating heavy or potentially dangerous machinery for at least 5 weeks after BREYANZI administration (5.9).

Find US and EU labels by drug, disease, regulatory designation and more

Quick Search – indication

The screenshot shows the 'Quick Search' interface. At the top, there is a search bar containing the text '"large b-cell lymphoma"' and a blue 'Search' button. To the right of the search bar is an 'Advanced search' button. Below the search bar is a 'Filter' section with several tabs: 'Country/Region', 'Topic', 'Document Type' (which is selected and highlighted in dark blue), 'Document Category', 'Date', 'Translation Status' (with a 'New' badge), and 'All other filters'. There is also a 'Reset Filters' button. Below the filter tabs is a search icon, a 'Select all' checkbox, a 'Clear all' button, and a 'Sort by' dropdown menu set to 'Frequency'. Below these are several filter buttons with counts: 'EPAR (119)', 'Supplemental Approval - BLA (95)', 'Opinion (26)', 'Evaluation Report (16)', 'CHMP opinion (14)', 'Product Miscellaneous (13)', 'Guideline (10)', 'Notification (10)', 'Press Release (10)', 'Original Approval - BLA (8)', 'Summary Basis Of Decision (6)', 'Evaluation Summary (5)', 'Product Approval Bulletin (5)', 'Meeting (4)', 'Notice of Compliance with Conditions (4)', 'Regulatory Decision Summary (4)', 'Supplemental Approval - NDA (4)', and 'Federal Register Announcement (2)'. At the bottom of the filter section are 'Cancel' and 'Apply' buttons.

Find all EPARs for an a disease/indication e.g., large b-cell lymphoma

1. Type "large b-cell lymphoma" into the keyword box
2. Open Document Type folder and select EPAR
3. Click Apply and Search

Results found using Quick Search are very targeted as Quick Search only searches the Titles, Abstracts and Reason for Update sections of the whole report – not the entire document PDF.

Find US and EU labels by drug, disease, regulatory designation and more

Quick Search – indication

"large b-cell lymphoma" **Search**

Filter

Country/Region Topic Document Type Document Category Date **New** Translation Status All other filters Reset Filters

Side by Side Viewer Showing 1-10 of 239 results

Customize Columns Sorted by Relevance

<input checked="" type="checkbox"/>	Summary	Title	Abstract	Last U
<input checked="" type="checkbox"/>	13-Dec-2016 V EU EN RD	EMA/688679/2016: Public Summary of Positive Opinion for Orphan Designation of valproic acid for the Treatment of Diffuse Large B-Cell Lymphoma, 13-Dec	This document provides the COMP Public Summary of Positive Opinion for Orphan Designation of valproic acid. - Applicant: ...	18-Oct
<input checked="" type="checkbox"/>	25-Jan-2023 V EU EN RD	EU/3/22/2656: Public Summary of Positive Opinion for Orphan Designation of odronextamab for the Treatment of Diffuse Large B-cell Lymphoma, 25-Jan-	This document provides the COMP Public Summary of Positive Opinion for Orphan Designation of odronextamab. - Applicant: ...	30-Jan
<input checked="" type="checkbox"/>	15-May-2018 V EU EN RD	EMA/178440/2018: Public Summary of Positive Opinion for Orphan Designation of polatuzumab vedotin for the Treatment of Diffuse Large B-cell	This document provides the COMP Public Summary of Positive Opinion for Orphan Designation of polatuzumab vedotin. - Applicant: ...	18-Oct

Set up an Alert

1. Click the Alert icon
2. Name the search in the pop-up and click Save

Save Search Query

Title "large b-cell lymphoma" EPAR Alert

Details

Query "large b-cell lymphoma"

Content Set Regulatory

Filters 2 Filters Applied

☒ Create Alert

Cancel **Save**

Search entire documents - including labels

Source Document Search

Find all US Labels that mention Wernicke's encephalopathy

1. Type "Wernicke's encephalopathy" into the keyword box
2. Select Document Type filter and Supplemental Approval - NDA and Original Approval - NDA
3. Click Apply and Search

The screenshot shows the Source Document Search interface. A red box highlights the search input field containing the text "wernicke's encephalopathy". Another red box highlights the blue "Search" button. A third red box highlights the "Document Type" filter button. Below the filters, a grid of document type buttons is shown, with "Supplemental Approval - NDA (6)" and "Original Approval - NDA (4)" highlighted. A red box also highlights the "Apply" button at the bottom right. A purple "New" badge is visible above the "Translation Status" filter. On the right side, there is a sidebar with a "Support" button and a notification bubble with the number "1".

Search input: "wernicke's encephalopathy"

Search button: Search

Filter: Document Type

Document Type filters: Country/Region, Topic, Date, Translation Status (New), Medical Devices Specialty, All other filters, Reset Filters

Search results filters: Supplemental Approval - NDA (6), Meeting (5), Original Approval - NDA (4), Curriculum Vitae (3), Law (3), Citizen Petition (2), EPAR (2), Pharmacovigilance Bulletin (2), Report (2), Checklist (1), Evaluation Report (1), Evaluation Summary (1), Guideline (1), Newsletter (1), Notification (1), Product Information (1), Product Miscellaneous (1), Regulation (1), Summary Basis Of Decision (1)

Buttons: Cancel, Apply

Compare packaging and labeling requirements across countries

Comparison Tables

The screenshot displays the 'Regulatory' section of a software interface. At the top, there are tabs for 'All', 'Comparison Tables', 'Intelligence Reports', 'Regulatory Summaries', and 'Source Documents'. The 'Comparison Tables' tab is active. Below this, there are filters for 'Drugs & Biologics' and 'Medical Devices & IVDs'. The main content area is divided into 'Browse' and 'Quick Search' sections. The 'Quick Search' section has a search bar with the text 'labeling' entered. Below the search bar, there are two columns of results. The left column is titled 'Product Information' and contains a link for 'Package Labeling Requirements'. The right column is titled 'Labeling and Promotion' and contains links for 'IVD Labeling Requirements', 'Medical Device Advertising Requirements', and 'Medical Device Labeling Requirements'. The 'Package Labeling Requirements' link is highlighted with a red box.

Regulatory

Comparison Tables

Quick Search

labeling

Product Information

- Package Labeling Requirements

Labeling and Promotion

- IVD Labeling Requirements
- Medical Device Advertising Requirements
- Medical Device Labeling Requirements

Are Mandatory Warning and Braille Language required?

1. Use the Filter tool to find the Comparison Tables with Labeling in the title
2. Choose Package Labeling Requirements

Compare Package and Labeling Requirements

Comparison Tables

Last Updated Date
30-Apr-2024

Global Comparison

My Regions

Apply Filters

Country/Region	Language	Language Notes	Mandatory Warnings	Mandatory Warnings Notes	MAH's Information	MAH's Information Notes
		provided that the same particulars appear in ...		requirements: special storage condition		
European Union	Not applicable	Language(s) of the Member States	Required	Special warning that the medicinal product must be kept out of sight ...	Required	Name and address of the MAH and, where applicable, the name of ...
Finland	English; Finnish; Swedish	Fimea accepts the English SmPC during regulatory procedures, if any c	Required	• Keep out of reach and sight of children: "Ei ...	In line with EU requirements	N/A
France	French	Other languages accepted provided that the same particulars appear in		Fimea accepts the English SmPC during regulatory procedures, if any common European procedures are used (CP, DCP, MRP). Other languages accepted provided that the same particulars appear in all languages.	In line with EU requirements	Additional national requirement: Name and

Pictograms, Logos, Tags Notes	Other Labeling Particulars	Regulatory Summary	Reference Document(s)
Symbols or pictograms designed to clarify certain information and oth ...	Other general label requirements include: Name, strength, ...	Product Information	European Parliament and Council Directive 2001/83/EC of 06-Nov-2001: The ...
• Products containing inflammable material must bear the interna ...	It is possible to use a common Nordic labelling for Sweden, Denmark, ...	Product Information	Administrative Regulation 3/2019: Labelling and Package Leaflets for Medicinal ...
• Products which may reduce the ability to drive or operate mach ...	The method of administration and, if necessary, the route of ...	Product Information	CSP, Regulatory Part, Fifth Part: Health Products (Art. R. 5112-1 to R. 5471-1) (as last ...

1. Click the filter icon to filter to only desired countries

3. Scroll to the right to reveal more data

4. Click three dots to reveal more information

4. Link to official documents and Regulatory Summaries

Dive Deep into Labeling requirements for a country

Regulatory Summaries

The screenshot shows the Cortellis Regulatory Summaries page. The 'Regulatory Summaries' tab is highlighted with a purple box. The 'Labeling, Packaging and Product Information Requirements' section is expanded, showing a list of countries with 'USA' highlighted by a purple box.

Regulatory CMC Intelligence

All Comparison Tables Intelligence Reports **Regulatory Summaries** Source Documents

Browse Search

Filter by Country / Region

Drugs and Biologics Medical Devices and IVDs

Authorities and Organizations

- Competent Health Ministries and Regulatory Agencies | Country Summaries
- European Institutions and Bodies | Overview
- European Heads of Medicines Agency | Overview

International and Regional Bodies

- Association of Southeast Asian Nations (ASEAN)
- Central American Integration System (SICA)
- Council for International Organizations of Medical
- Council of Europe
- Eurasian Economic Union (EAEU)

Medical Devices Regulatory Framework

Algeria, Argentina, Australia, Austria, Belgium, Brazil, Bulgaria, Canada, Chile, China, Colombia, Costa Rica, Croatia, Czech Republic, Denmark, EAEU, Egypt, Estonia, European Union, Finland, France, Germany, Greece, Guatemala, Hong Kong, Hungary, India, Indonesia, Iraq, Ireland, Israel, Italy, Japan, Jordan, Kenya, Latvia, Lebanon, Lithuania, Malaysia, Mexico, Morocco, Netherlands, New Zealand, Nigeria, Norway, Panama, Peru, Philippines, Poland, Portugal, Romania, Russian Federation, Saudi Arabia, Serbia, Singapore, Slovakia, Slovenia, South Africa, South Korea, Spain, Sweden, Switzerland, Taiwan, Thailand, Tunisia, Vietnam

Labeling, Packaging and Product Information Requirements

Algeria, Argentina, Australia, Austria, Belgium, Brazil, Bulgaria, Canada, Chile, China, Colombia, Costa Rica, Croatia, Czech Republic, Denmark, EAEU, Egypt, Estonia, European Union, Finland, France, Germany, Greece, Guatemala, Hong Kong, Hungary, India, Indonesia, Iraq, Ireland, Israel, Italy, Japan, Jordan, Kenya, Latvia, Lebanon, Lithuania, Malaysia, Mexico, Morocco, Netherlands, New Zealand, Nigeria, Norway, Panama, Peru, Philippines, Poland, Portugal, Romania, Russian Federation, SICA, Saudi Arabia, Serbia, Singapore, Slovakia, Slovenia, South Africa, South Korea, Spain, Sweden, Switzerland, Taiwan, Thailand, Tunisia, Turkey, **USA**, Ukraine, United Arab Emirates, United Kingdom, Venezuela, Vietnam

1. Click Regulatory Summaries

2. Scroll down to Labeling, Packaging and Product Information Requirements

3. Click your country, e.g.; USA

Dive Deep into Product Information for a country

Regulatory Summaries

The screenshot shows a web application interface for regulatory documents. On the left is a sidebar with a table of contents. The main content area displays the text for a specific question (Q6.3).

Q6.3 What specific layout should the labeling/packaging adhere to in the country/region?

Refer to the following sections of [21 CFR part 201: Labeling \(Table of Contents\)](#) (IDRAC 8597):

- 21 CFR 201.1: Name and place of business of manufacturer, packer, or distributor
- 21 CFR 201.2: National Drug Code (NDC)
- 21 CFR 201.10: Statement of ingredients (active and inactive)
- 21 CFR 201.15: Prominence of required label statements
- 21 CFR 201.17: Location of expiration date
- 21 CFR 201.18: Significance of control numbers (Lot number)
- 21 CFR 201.20(a): FD&C Yellow No. 5
- 21 CFR 201.25: Bar code label requirements. Additionally refer to [MAPP: Chapter 5231.1: CDER Barcode Inquiries, 02-Oct-2018](#) (IDRAC 283674).

Specific to Prescription Drugs and/or Insulin

- 21 CFR 201.50: Statement of identity (established name)
- 21 CFR 201.51: Declaration of net quantity of contents
- 21 CFR 201.55: Statement of dosage (e.g., Recommended Dosage: see Prescribing Information)

For prescription drugs, "Rx Only" should be mentioned.

The FDA's [Guidance for Industry: Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors, May-2022](#) (IDRAC 347404) provides a set of principles and recommendations for ensuring that critical elements of a product's container label and carton label are designed to promote safe dispensing, administration, and use of the product. It applies to human prescription drug and biological products.

Risk assessment during the design stage can reduce the risk of medication errors. For more information and recommendations on packaging approaches and analytical methods for risk assessments refer to the FDA's [Guidance for Industry: Safety Considerations for Product Design to Minimize Medication Errors \(Final\), Apr-2016](#) (IDRAC 226762).

1. Consistent Q&A format across all countries/regions provides expert, consistent guidance for each country
2. Link to official documents
3. Export and set up Alerts from the icons in the upper right-hand corner

English Translations of Source documents

Machine Translations

Medicinal Products Act of 24-Aug-1976 (Arzneimittelgesetz - AMG) (Amended Version of 03-Jun-2021)

Valid 347848 Germany Reference Document Law **Translation: Machine Translation**

Drugs and Biologics

Document

Revision 09-Jun-2021 German

Ein Service des Bundesministeriums
sowie des Bundesamts für

Gesetz über den Verkehr mit Arzneimitteln (Arzneimittelgesetz - AMG)

AMG

Ausfertigungsdatum: 24.08.1976

Vollzitat:

"Arzneimittelgesetz in der Fassung der Bekanntmachung vom 12. Dezember 2005 (BGBl. I S. 3394), das zuletzt durch Artikel 9 des Gesetzes vom 3. Juni 2021 (BGBl. I S. 1309) geändert worden ist"

Stand: Neufassung durch Bek. v. 12.12.2005 I 3394;
zuletzt geändert durch Art. 1 V v. 19.5.2021 I 1164

Hinweis: Änderung durch Art. 9 G v. 3.6.2021 I 1309 (Nr. 28) textlich nachgewiesen, dokumentarisch noch nicht abschließend bearbeitet

Fußnote

(+++ Textnachweis Geltung ab: 6.6.1986 +++)
(+++ Zur Anwendung vgl. §§ 63j, 109, 141 +++)
(+++ Amtlicher Hinweis des Normgebers auf EG-Recht:
Umsetzung der
EURL 84/2010 (CELEX Nr.: 32010L0084)
EURL 62/2011 (CELEX Nr.: 32011L0062)
EURL 24/2011 (CELEX Nr.: 32011L0024) vgl. G v. 19.10.2012 I 2192 +++)

Das G wurde als Artikel 1 G v. 24.8.1976 I 2445 vom Bundestag mit Zustimmung des Bundesrates beschlossen.
Es ist mit Ausnahme d. § 78 am Art. 10 dieses G am 1.1.1978 in Kraft getreten.

1.View at the top what type of translation is available for that document

2.Scroll to the Document

3.Click the Machine Translation Document icon and select preferred format to open

Machine Translated by Google

A service of the Federal Ministry of Justice and Consumer Protection
and the Federal Office of Justice | www.gesetze-im-internet.de

Law on the trade in medicinal products (Medicines Act - AMG)

AMG

Date of issue: August 24, 1976

Full quote:

"Medicinal Products Act in the version published on December 12, 2005 (BGBl. I p. 3394), the most recent has been changed by Article 9 of the law of June 3, 2021 (BGBl. I p. 1309)"

Was standing: Rewritten by Bek. December 12, 2005 I 3394;
last amended by Art. 1 V v. May 19, 2021 I 1164

Note: Change by Art. 9 G v. June 3, 2021 I 1309 (No. 28) proven textually, still documented not finalized

footnote

(+++ Text reference valid from: June 6, 1986 +++)
(+++ For application see §§ 63j, 109, 141 +++)
(+++ Official reference from the standard provider to EC law:
Implementation of
EURL 84/2010 (CELEX No.: 32010L0084)
EURL 62/2011 (CELEX No.: 32011L0062)
EURL 24/2011 (CELEX No.: 32011L0024) cf. G v. 10/19/2012 I 2192 +++)

The G was introduced as Article 1 G of. August 24, 1976 I 2445 passed by the Bundestag with the consent of the Bundesrat.
It is with the exception of d. § 78 according to Article 10 of this G came into force on January 1, 1978.
Legal abbreviation: Inserted. by Art. 1 No. 1 G v. July 30, 2004 I 2031 mWv August 6, 2004

Table of contents

English Translations of Source documents

Human Translations

Federal Law N 61-FZ of 12-Apr-2010: On Circulation of Medicinal Products (Consolidated Version up to Amendment the Federal Law N 1-FZ of 30-Jan-2024)

Valid 209259 Russian Federation Reference Document Law Translation: Cortellis Translation

Drugs and Biologics

Clinical Research Compl

File 1
▶ Cortellis Translation English version
▶ Original file

12 April 2010 No. 61-FZ

RUSSIAN FEDERATION
FEDERAL LAW
ON CIRCULATION OF MEDICINAL PRODUCTS*

Adopted
by the State Duma
on 24 March 2010

Approved
by the Council of Federation
on 31 March 2010

(as amended by Federal Laws No. 192-FZ of 27/07/2010,
No 271-FZ of 11/10/2010, No. 313-FZ of 29/11/2010,
No. 409-FZ of 06/12/2011, No. 93-FZ of 25/06/2012,
No. 262-FZ of 25/12/2012, No. 185-FZ of 02/07/2013,
No. 317-FZ of 25/11/2013, No.33-FZ of 03/12/2014,
No.313-FZ of 10/22/2014, No 429-FZ of 22/12/2014,
No 34-FZ of 08/03/2015, No. 160-FZ of 29/06/2015,
No. 233-FZ of 13/07/2015, No. 241-FZ of 13/07/2015,
No. 262-FZ of 13/07/2015, No. 374-FZ of 14/12/2015,
No. 389-FZ of 29/12/2015, No. 163-FZ of 02/06/2016,
No. 261-FZ of 03/07/2016, No. 305-FZ of 03/07/2016,
No. 350-FZ of 03/07/2016, No. 242-FZ of 29/07/2017,
No. 278-FZ of 29/07/2017; No 425-FZ of 28/12/2017;
No. 140-FZ of 04/06/2018, No. 449-FZ of 28/11/2018,
No. 511-FZ of 27/12/2018, No. 134-FZ of 06/06/2019
No. 240-FZ of 26/07/2019, No. 297-FZ of 02/08/2019,
No. 462-FZ of 27/12/2019, No. 475-FZ of 27/12/2019,
No. 67-FZ of 26/03/2020, No. 98-FZ of 01/04/2020,
No. 105-FZ of 03/04/2020, No. 206-FZ of 13/07/2020

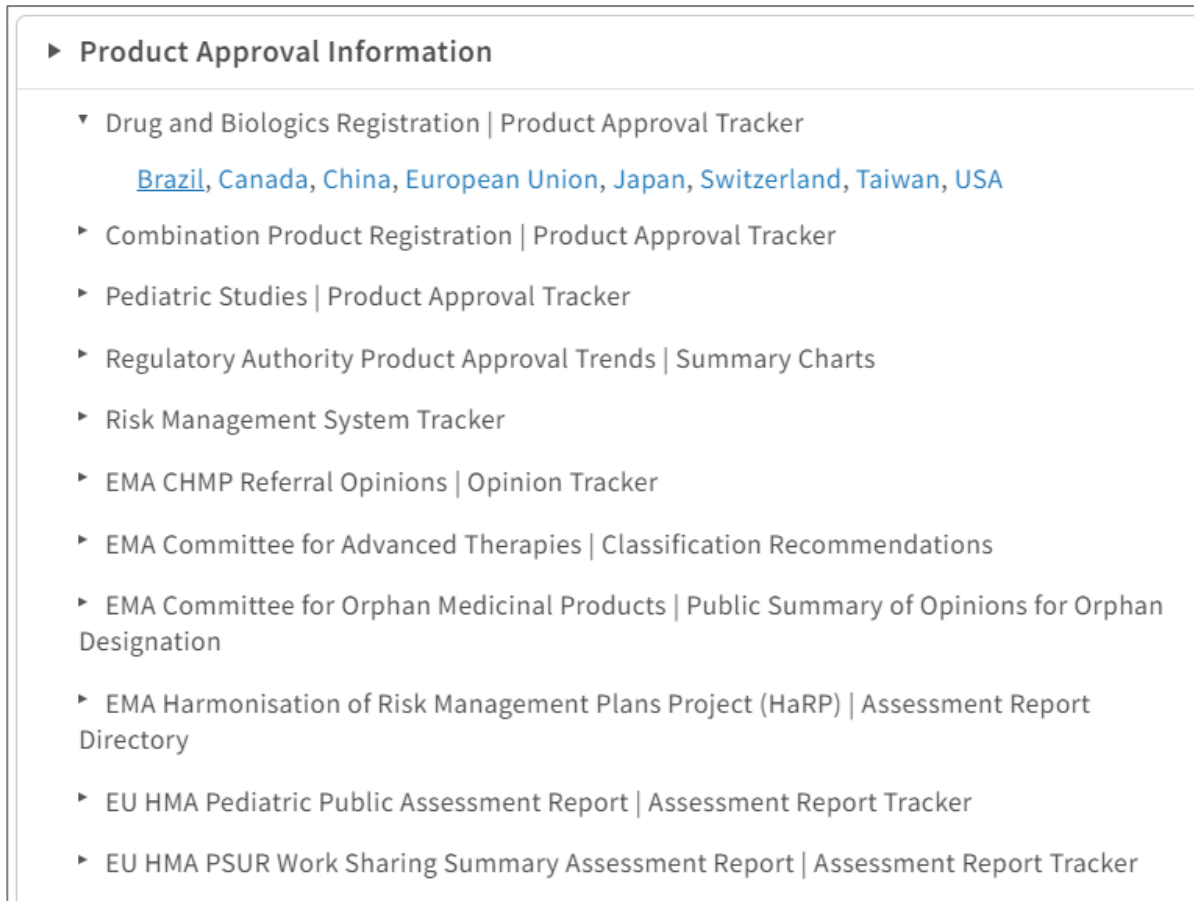
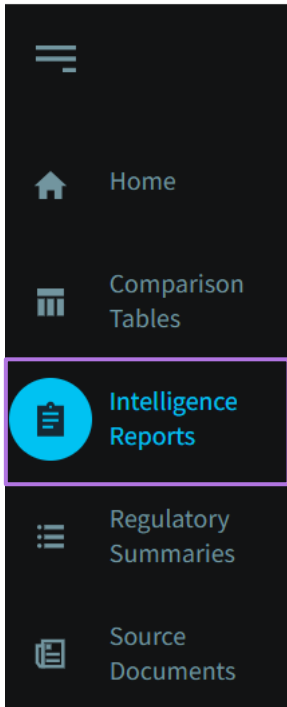
1.View at the top what type of translation is available for that document

2.Human Translations will be indicated by either Cortellis Translation, Authority Official or Authority Unofficial

3.The translation will be contained in the document with the native language version

Assess the competition - find approved drugs for thousands of indications globally

Product Approval Trackers - Brazil, Canada, China, EU, Japan, Switzerland, Taiwan and USA



1. Go to the Regulatory Intelligence Reports
2. Scroll down to Product Approval Information
3. Click the country link to open the tables

Assess the competition - find approved drugs for thousands of indications globally

Product Approval Trackers cover Brazil, Canada, China, EU, Japan, Switzerland, Taiwan and USA

Drug Submission and Product Approval List Overview

Valid

136082

USA

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) contains the list of New Drug Applications (NDAs), Biologics License Applications (BLAs), biosimilars and supplements approved from 1997 by the United States Food and Drug Administration (FDA). Generics (ANDA) are out of scope of this table and are not available in CRI.

Biological Types:

- Therapeutic biologics
- Allergenic: patch tests used to diagnose the causes of contact dermatitis. Extracts used to diagnose and treat rhinitis, allergic sinusitis and conjunctivitis, and bee stings.
- Blood and blood products: blood and blood components used for

Last Updated Date

10-Jun-2024

Added Date

09-Jan-2012

Document

None

English

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Assess the competition - find approved drugs for thousands of indications globally

Product Approval Trackers - Brazil, Canada, China, EU, Japan, Switzerland, Taiwan and USA

Name	Active Ingredient(s)	Application/Submission Type	Application Number	Active Substance Status	FDA Biological Type	FDA Chemical Type	Product Type	Dosage Form	Route of Administration	Therapeutic Area	Indication(s)
RAYOS	prednisone	<div> <div> Sort A to Z Sort Z to A Sort by Color Sheet View Clear Filter From "Application/Submi..." Filter by Color Text Filters Search <input checked="" type="checkbox"/> (Select All) <input checked="" type="checkbox"/> BLA <input checked="" type="checkbox"/> BLA (biosimilar) <input checked="" type="checkbox"/> NDA <input checked="" type="checkbox"/> sBLA <input checked="" type="checkbox"/> sBLA (biosimilar) <input checked="" type="checkbox"/> sNDA </div> <div>OK Cancel</div> </div>	202020/013	Known active substance	Not applicable	New dosage form	Drugs & Biologics	Tablet	Oral	Cancer ; Dermatological disorders ; Endocrine disorders ; Eye disorders ; Gastrointestinal disorders ; Hematologic diseases ; Hematologic diseases ; Immunological disorders ; Infections ; Musculoskeletal and connective tissue disorders ; Neurological disorders ;	For the treatment of the following conditions: Allergic Conditions, De Diseases, Endocrine Conditions, G Diseases, Hematologic Diseases, N Conditions, Nervous System Condi Conditions, Conditions Related to Transplantation, Pulmonary Disea Conditions, Rheumatologic Condi Infectious Diseases.
ORAPRED ODT	prednisolone sodi		21959/014	Known active substance	Not applicable	New dosage form	Drugs & Biologics	Tablet	Oral	Cancer ; Dermatological disorders ; Endocrine disorders ; Eye disorders ; Gastrointestinal disorders ; Hematologic diseases ; Neurological disorders ; Other disorders (systemic disorders) ; Respiratory disorders	In the following diseases or condit conditions, Dermatologic Diseases Conditions, Gastrointestinal Disea Diseases, Neoplastic conditions, N conditions, Ophthalmic conditions related to organ transplantation, F Diseases, Renal conditions, Rheum Conditions and Specific Infectious
HEMADY	dexamethasone		211379/006	Known active substance	Not applicable	New combination ; New formulation or new manufacturer	Drugs & Biologics	Tablet	Oral	Cancer	In combination with other anti-my the treatment of adults with multip
CALQUENCE	acalabrutinib		210259/010	New active substance	Not applicable	New molecular entity (NME)	Drugs & Biologics	Capsule	Oral	Cancer	CALQUENCE is indicated: - For the treatment of adult patient lymphoma (MCL) who have receive therapy. - For the treatment of adult patient lymphocytic leukemia (CLL) or sma lymphoma (SLL).
LYMPRA	rituximab		210259/003	New active substance	Not applicable	New molecular entity (NME)	Drugs & Biologics	Tablet	Oral	Cancer	LYMPRA is indicated:

Filter the tables by Therapeutic area, Application/Submission type and more

Assess the competition - find approved drugs for thousands of indications globally

Product Approval Trackers - Brazil, Canada, China, EU, Japan, Switzerland, Taiwan and USA

Company	Legal Basis	Submission Date	Receipt Date	Advisory Committee Meeting Dat	Review Cycles	Approval Dat	Review Type	Orphan Designation	Orphan Designation Dat	Priority Review Vouche	Approval Type	Review Center	Review Off
Horizon Therapeutics USA Inc.	505(b)	08-Mar-2024	08-Mar-2024		Not available	05-Jun-2024	Standard review	No		No	No	CDER	Immunology New drugs
Concordia Pharmaceuticals Inc.	505(b)	01-Mar-2024	01-Mar-2024		Not available	05-Jun-2024	Standard review	No		No	No	CDER	Immunology New drugs
Dexcel Pharma Technologies Ltd.	505(b)	22-Feb-2024	22-Feb-2024		Not available	05-Jun-2024	Standard review	No		No	No	CDER	Oncologic D
AstraZeneca UK Ltd.	505(b)	23-May-2024	23-May-2024		Not available	05-Jun-2024	Standard review	No		No	No	CDER	New drugs ;

Compare Submission Dates and Approval Dates to understand how long approvals are taking and filter to Regulatory Designations

Assess the competition - find approved drugs for thousands of indications globally

Product Approval Trackers - Brazil, Canada, China, EU, Japan, Switzerland, Taiwan and USA

Review Category/Division	Boxed Warni	Medication Guide	REMS	Pediatric Us	FDA Supplement Type	FDA Supplement Rationale	Link to Product Approval Document
Rheumatology and transplant medicine	No	No	No	Yes	Non-efficacy supplement	Provided for revisions to the labeling consistent with new safety information that pertains to the risk of activation of latent infections and special pathogens, and of Kaposi's sarcoma.	385085
Rheumatology and transplant medicine	No	No	No	Yes	Non-efficacy supplement	Provided for revisions to the labeling consistent with new safety information that pertains to the risk of activation of latent infections and special pathogens, and Kaposi's sarcoma.	385068
Not available	No	No	No	No	Non-efficacy supplement	Provided for revisions to the labeling consistent with new safety information that pertains to the risk of activation of latent infections and special pathogens, and Kaposi's sarcoma.	385058
Not available	No	No	No	No	Non-efficacy supplement	Provided for revisions to the labeling with agreed upon changes to the text consistent with the new safety information pertaining to the risk of cardiac arrhythmia including ventricular arrhythmia under Highlights of Prescribing Information, 5.5 Cardiac Arrhythmias, 5.6 Hepatotoxicity, Including Drug-Induced Liver Injury, 6.2 Postmarketing Experience, 17 Patient Counseling Information sections and Patient Package Insert.	385051

Filter to find products with Boxed Warnings, Med Guides and REMS

Click the links to view the Approval Documents

Assess the competition – find approved drugs for thousands of indications globally

Cortellis Competitive Intelligence

All

"b-cell lymphoma"

Index

Full Text

Explore

en

Beth Wise

GenAI Enhanced Search

Advanced search

Structure search

Search history

< Back

Forward >

Search Results

Timeline & Success Rates

Related Content

Analyze

Save and Alert

Download

546 results found for index Search for the search term 'lymphoma' with filter(s) applied: B-cell lymphoma

First

Previous

1

2

3

4

5

6

Next

Last

Report Type

Show selected only

Broker Research (91091)

Clinical Trials (16251)

Companies (2952)

Conferences (5852)

Deals (5249)

Disease Briefings (32)

Drugs (2268)

Event Transcripts (6940)

Experimental Pharmacology (50436)

Literature (55810)

Patents (20408)

Pharmacokinetics (12975)

Press Releases (14118)

Results

Per page: 100

Sort by: Relevance

Order Columns

View

Drug Name	Other Drug Names	Active Companies	Active Indications	Target-based Actions	Highest Status
		Filters : [0]	Filters : [0]	Filters : [0]	Filters : [0]
ibritumomab tiuxetan	111In-2B8 ; 111In-anti-CD20, IDEC ; 111In-ibritumomab tiuxetan ; 90Y-2B8 ; 90Y-anti-CD20, IDEC ; 90Y-ibritumomab tiuxetan ; BAY86-5128 ; DE-00749 ; IDEC-In2B8 ; IDEC-Y2B8 ; SHL-749 ; Zevalin ; ibritumomab tiuxetan ;	Acrotech Biopharma Inc; CASI Pharmaceuticals Inc; FUJIFILM Holdings Corp; Mundipharma International Corp Ltd; Servier Canada Inc	B-cell lymphoma; center lymphoma; Hodgkin lymphoma		
loncastuximab tesirine	ADCT-402 ; Lonca ; Lonca-T ; MT-2111 ; Zynlonta ; loncastuximab tesirine ; loncastuximab tesirine-lpyl	ADC Therapeutics SA; Mitsubishi Tanabe Pharma Corp; Overland ADCT BioPharma (CY) Limited; Swedish Orphan Biovitrum AB (Publ)	B-cell lymphoma; lymphocytic leukemia; large B-cell lymphoma; center lymphoma; Hematological neoplasms; grade B-cell lymphoma; Lymphoplasma; lymphoma; Mantle		
pralatrexate	10-propargyl-10-deazaaminopterin ; DHFR inhibitor (anticancer), Allos ; DHFR inhibitor (anticancer), Memorial Sloan-Kettering ; Difolta ; Foflotyn ; PDX, Allos ; pralatrexate	Acrotech Biopharma Inc; CASI Pharmaceuticals Inc; Mundipharma International Corp Ltd; Servier Canada Inc	Anaplastic large lymphoma; Angioimmunoblastic lymphoma; Cutaneous lymphoma; Follicular lymphoma; Hepatic cell lymphoma; Lymphoma; T-cell lymphoma; T-cell		

SHOW ALL FILTERS

Search Country/Territory

Look up

Select filter view

Free

Therapy Area

Indication

Company

Status

Country/Territory

Target-based Actions

Other Actions

Technologies

Added Date

Last Change Date

Highest Status

Highest Status at Termination

Reason for Discontinuation

☐ US (299)

☐ China (179)

☐ Europe (33)

☐ Australia (30)

☐ UK (23)

☐ South Korea (1)

☐ Japan (20)

☐ Canada (19)

☐ Taiwan (15)

☐ Germany (12)

☐ Israel (10)

☐ Switzerland (1)

Search on over 2,000 global indications

Use country filters to find products globally

New - Summary Intuitive Search

Search across countries on questions in the Summaries

The screenshot shows the 'Regulatory' section of a website. At the top, there are navigation tabs: 'All', 'Comparison Tables', 'Intelligence Reports', 'Regulatory Summaries', and 'Source Documents'. The 'Regulatory Summaries' tab is highlighted with a purple box and has a 'New' badge. Below the tabs, there are two buttons: 'Browse' and 'Search'. The 'Search' button is highlighted with a purple box. Below the buttons, there is a heading: 'Smarter search outcomes and suggestions with our new intuitive search!'. Below this heading is a search input field with the text 'what specific layout' and a magnifying glass icon. Below the input field, there is a dropdown menu with three suggestions: 'What specific layout should the information addressed to healthcare professionals/SmPC adhere to in the country/re...', 'What specific layout should the labeling/packaging adhere to in the country/region?', and 'What specific layout should the package leaflet/patient information/package insert adhere to in the country/region?'. The entire search interface is highlighted with a purple box.

1. Click Summaries
2. Click Search
3. Start typing in a question from the Summaries
4. Select question from the drop-down

New - Summary Intuitive Search

Search across countries on questions in the Summaries

53 results found for

'What specific layout should the labeling/package adhere to in the country/region?'

Filters

Country/Region Topic Last Updated Date

Sorted by Relevance Expand All Collapse All

Clear Filters

Summary

1 27-Dec-2023 V

EEU EN RS

Product Information

This document summarizes the regulatory requirements for the Information for Healthcare Professionals (or Summary of Product Characteristics, SmPC), package insert (package leaflet or patient information) and Labelling (Packaging Information).

Country/Region: Eurasian Economic Union
IDRAC Number: 322129
Last Updated Date: 27-Dec-2023

What specific layout should the labeling/package adhere to in the country/region? ^

Information to be contained in the primary packaging On the primary (inner) packaging of a medicinal product (except for intended for medicinal plant raw material) the following information is indicated: Commercial name of the medicinal product; INN name (if any) or a common accepted (generic) name; Pharmaceutical form; strength and/or potency and/or concentration (if applicable) of the active pharmaceutical substance(s); Quantity of the medicinal product in the package; The route of administration; Name or logo of marketing authorization holder; Batch number; Expiry date ("valid until"). Information to be contained in the secondary packaging The following information is indicated on the secondary packaging or, if it is not available, on the primary packaging of the medicinal product: Commercial name of the medicinal product INN (if available) or common (generic) name; Name of marketing authorization holder and manufacturer of the medicinal product; Address of marketing authorization holder and manufacturer of the medicinal product; The pharmaceutical form; Strength and/ or activity and/ or concentration (if applicable) of the active pharmaceutical substance(s); Quantity of the medicinal product in the package; Information on the composition of the medicinal product; Batch number; Manufacturing date; Expiration date ("valid until"); Storage conditions and, if necessary, transportation; Route of administration Prescription status; Warning labels. For packaging of active pharmaceutical substances: Commercial name of the active pharmaceutical substance (if available); INN or common/generic name; Manufacturer's name and address of the pharmaceutical substance; Batch number; Manufacturing date; Quantity of active pharmaceutical substance in the package; Expiration date (valid until) or, if provided, the date of re-testing; Storage conditions; Use The following information is to be indicated on the transport container of packaging of bulk products: Commercial name of the medicinal product; Dosage form; INN (if available) or common (generic) name; Dosage and (or) activity and (or) concentration (if applicable) of the active pharmaceutical substance(s); Manufacturer's name and address of the medicinal product; Quantity of the medicinal product in the package and (or) the number of packages in the transport container; Storage conditions and, if necessary, transport conditions; Batch number; Manufacturing date; Expiry date ("valid until").

2 09-Feb-2024 V

AT EN RS

Product Information

This document summarizes the regulatory requirements for the Information for Healthcare Professionals (or Summary of Product Characteristics, SmPC), package insert (package leaflet or patient information) and Labelling (Packaging Information).

Country/Region: Austria
IDRAC Number: 32707
Last Updated Date: 09-Feb-2024

What specific layout should the labeling/package adhere to in the country/region? ^

The format of the labeling has to comply with the QRD template. Fonts: Printed unconnected letters of the Latin alphabet and Arabic numbers have to be used. Size: The type size of the product's name and, if enough space is available, of all other information should be at minimum 1.8 mm (8 points). The following information shall be included in the labeling (this applies to outer packaging and inner packaging, except if the inner packaging is too small, as it is the case for blisters and for containers with volumes less or equal than 10 ml): Name of the medicinal product (a fantasy name or a current scientific name, if it's no fantasy name a short version of the applicant or the trademark has to be added to the name. In addition, the strength and pharmaceutical form has to be mentioned. If applicable, a reference if the product is indicated for use in babies, children or adults. If the product contains up to three active ingredients, the active ingredients (INN) have to be mentioned below the product's name ("Wirkstoff(e):..."). Name and location of the marketing authorization holder: the word "Zulassungsinhaber" (MA holder) or "Registrierungsinhaber" (registration holder) or "Pharmazeutischer Unternehmer" (pharmaceutical company) must be placed in front of the MAH's name. Distributor: It is possible to state the distributor in the outer labeling, however, not mandatory. For medicinal products authorised according to §7 Austrian Medicinal Products Act, the declaration, modification or deletion of a distributor in Austria is considered as a notification. This can be included with any text-relevant variation, or if no such pending, simply notified by sending the information to the appropriate mailbox (rms@basg.gv.at, basg-cms@basg.gv.at or nat@basg.gv.at) respectively. For medicinal products registered according to §911, 11a or 12 Austrian Medicinal Products Act, such a change is considered as a notification according to § 24 (6) Austrian Medicinal Products Act. The form Formblatt F_209 should be used. No use of this form is needed if the declaration, modification or deletion of a distributor in Austria is to be notified together with any other variation. Marketing authorization number ("Z. Nr." or "Zul. Nr." or "R. Nr." or "Reg. Nr." or "R-Nr." or "Z.-Nr." has to be placed in front of the MA number) Composition - quantitative and qualitative composition of the active ingredient(s) and those excipients known to have a recognized action or effect (for further information see NTA Volume 3B, Guidelines - Excipients in the labeling and package leaflet of medicinal products for human use, October 2017). All excipients have to be given in injectable products, topical medicinal products, and eye drops. In divisible pharmaceutical forms the quantity has to be stated with relevance to the treatment unit. In non-divisible pharmaceutical forms and in infusion fluids the quantity stated has to be related to a unit, which is useful for the calculation of the amount of ingredients per single dose. The ingredients have to be stated with their international non-proprietary names of the WHO or, if not available, with other usual names. Pharmaceutical form and Quantity of content in the packaging in number (e.g., tablets), volume or weight, respectively. Safety features enabling wholesale distributors and persons authorized or entitled to supply medicinal products to the public to verify the authenticity of the medicinal product and identify individual packs as well as a device allowing verification of whether the outer packaging has been falsified if stipulated by article 54a of Directive 2001/83/EC. In bundle packages the contained single packages have to be labeled with "Teil einer Bündelpackung, Einzelverkauf unzulässig". The outer package of the bundle package has to contain at least information concerning the name of the product, quantity of content, pharmaceutical form, kind of application, lot number, expiry date, short name of the MAH, and the notice "Bündelpackung, Verkauf in Teilmengen unzulässig". If the outer package is transparent, it is not necessary to label it. Route of administration (e.g., in the case of oral forms: "zum Einnehmen") A space has to be left for indicating the prescribed dosage by the pharmacist. Lot number ("Ch. Nr.", "Ch." or "Lot." has to be placed in front of the lot number). Expiry date: The label has to contain an uncoded date of expiry stating at least the month and year of the expiry date, calculated from the manufacturing date. If the month is written as word, the short version has to contain

1. Use filters to narrow down, e.g.; use My Country Filter under Countries/Region
2. Click Expand all to view answers on the page
3. View Countries on the left

Feedback poll/Wrap- up

What did I learn that will support me the most in my role?

1. *Running searches and setting up alerts* - track US and EU labels by drug, disease, regulatory designation and more
2. *Comparison Tables* - compare packaging and labelling requirements on 80+ countries, for example, are Mandatory Warnings or Braille language required?
3. *Regulatory Summaries* - curated reports providing the guidance I need on labeling policy
4. *Human and machine English translations* - available for every valid source document
5. *Access the competition* - find approved drugs for thousands of indications globally

My additional feedback on Cortellis/today's training is:

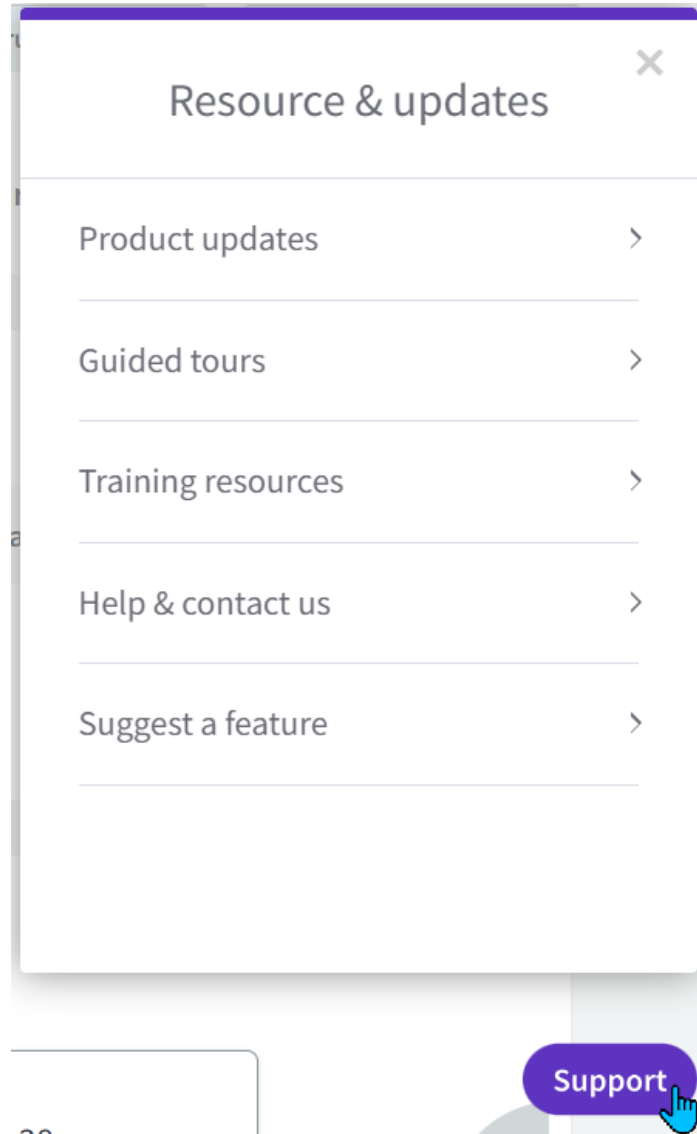
Get assistance with Cortellis

In-product guidance to assist you with your questions

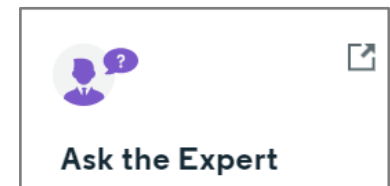
- Click at the question mark at the bottom of the screen

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- Guided tours - walk through the Cortellis platform
- Training resources - recorded trainings, Quick guides and short videos
- Ask the Expert (on Regulatory homepage)





Thank you! Questions?

Beth.Wise@Clarivate.com

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