

The Weekly Update – Never miss important regulatory changes

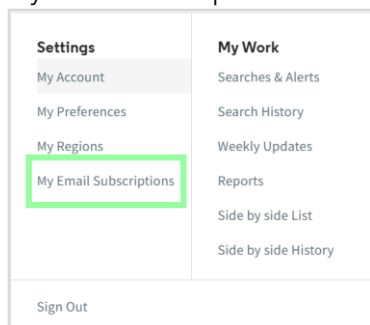
***Note:** The email versions of the Weekly Update, and its previous version the Weekly Alert, are deactivated by default. Even if you previously subscribed to the Weekly Alert you need to turn on the Weekly Update to start or continue receiving emails.

Follow this guide to quickly set up your Weekly Update with all the new and updated regulatory documents you need to ensure compliance. You'll then receive an email every Monday with a link to your customized Weekly Update.

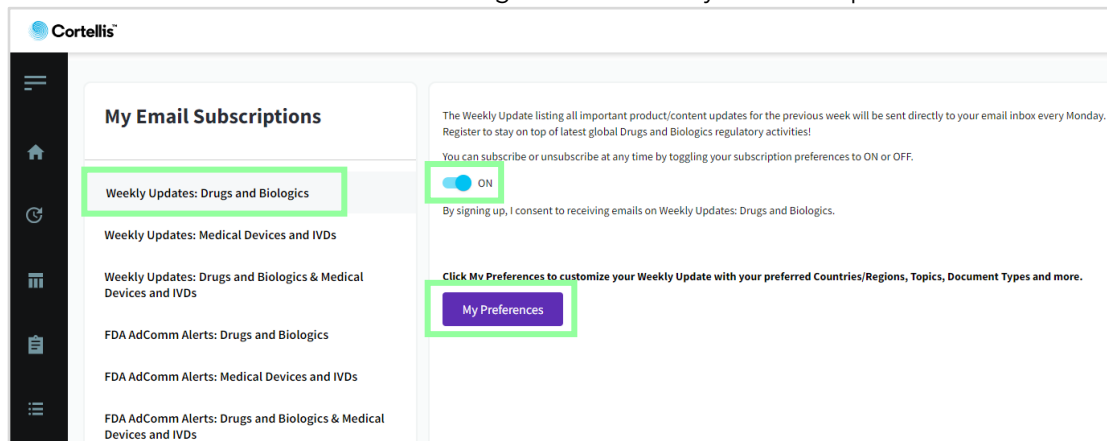
Example: Let's create a Weekly Update that covers guidances on Pharmacovigilance and Risk Management for North America and European countries for the Drugs and Biologics content.

Turning on your Weekly Updates

1. After logging into Cortellis hover over your name in the upper right-hand corner of the screen and select My Email Subscriptions under Settings.



2. Select the content type you want to track. For this example, select Drugs and Biologics. What's visible to you is based on your subscription so all options might not be shown.
3. Next toggle the button from OFF to ON.
4. To customize click My Preferences. If you do not choose any customizing options, your Weekly Update will cover all content for the countries/regions covered in your subscription.



Customizing your Weekly Updates

5. Use the filters on the left to Select your preferences. For this example, select Country/Region and click on the North American and European countries you want to track.
6. Next click on Topic and select Pharmacovigilance Technovigilance Risk Management, then Document Type and Guideline. Be sure to click Apply when you are done with your filters.

Your Weekly Update is now configured.

Select your preferences

19 Country/Region

Topic

Document Type

Document Category

Translation Status

omm Alerts: Medical Devices and IVDs

omm Alerts: Drugs and Biologics & Medical and IVDs

Q

Select All

Clear All

Sort By

Frequency

USA (73823)

European Union (58357)

Canada (8666)

France (5368)

Japan (3933)

Brazil (2974)

United Kingdom (2527)

International (2447)

China (2231)

South Korea (2171)

Italy (2055)

Switzerland (2027)

Germany (1979)

Denmark (1788)

Portugal (1708)

Taiwan (1610)

Turkey (1562)

Spain (1505)

India (1456)

Sweden (1343)

Czech Republic (1163)

Greece (1105)

Argentina (1062)

Belgium (1052)

Australia (1012)

Ireland (1010)

Austria (972)

Netherlands (935)

Russian Federation (841)

South Africa (832)

Malaysia (806)

Finland (756)

Hong Kong (749)

Poland (746)

Mexico (730)

Cancel

Apply

Weekly Update Email

You will begin receiving your Weekly Update email the Monday after set up. Click the link to open the Weekly Update. If you are not logged in to Cortellis you will be propted to log in first.

Cortellis Regulatory Intelligence Weekly Update - Drugs and Biologics - Volume 2024 - 39

CA

Cortellis Alerts NonProd

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Tue 10/1/2024 4:54 AM

Dear Cortellis Regulatory Intelligence User,

Please find our

Weekly Update - Drugs and Biologics

2024 Volume 39 of 23-Sep-2024 - 29-Sep-2024.

The Cortellis Regulatory Intelligence Weekly Update provides you with a summary of the Global Regulatory Landscape by highlighting latest updates (including new and updated official and exclusive expert documents for each country or territory) in a weekly basis.

The Cortellis Regulatory Intelligence Team

Subscription

This email has been sent to you as you consent to receiving emails on Weekly Updates: Drugs and Biologics. Please add us to your address book or 'Safe Senders List' to guarantee receipt of our emails.

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Weekly Update



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Cortellis Regulatory Intelligence Weekly Update: Drugs and Biologics

Your inside source of product & regulatory updates

Volume 39, 23-Sep-2024 to 29-Sep-2024

See Conference Reports and product updates under Latest News

Latest News

CONFERENCE REPORT [CRI Work Instruction Reference Document Creation and Lifecycle Management \(Basic Editorial Actions in RICS\)](#)

This report encapsulates the highlights from the 16th International Drug Information Conference/DIA Suzhou Annual Meeting and Exhibition, held from May 17 to 19, 2024. The conference, themed "Embracing Innovative Technology, Expanding Health Horizon," convened nearly a thousand global regulatory lawmakers, doctors, drug research experts, and patient representatives. The report delves into key topics such as the promotion of biomedicine industry development through enhanced international cooperation, the challenges and opportunities of AI in drug research and development, the evolution of decentralized clinical trials with a focus on compliance, quality, and safety, and the implementation of conditional approvals. It also provides a fresh perspective on the layout of the emerging market, particularly the Middle East, discusses improvements to the Marketing Authorization Holder (MAH) system to assist in the R&D of new drugs, and explores the role of pharmacovigilance in the development of drugs for rare diseases. By Boon Cheng Chew | Senior Content Editor, Cortellis Regulatory Intelligence

Expanded Singapore Product Approval Summaries (New Chemical and Biological Entities)

We have expanded product approvals scope to incorporate the drug benefit-risk assessment summary reports published by the Singapore Health Science Authority (HSA) since 2020. This content expansion aims to support the growing interest in Singapore's drug approval processes following its participation in ACCESS Consortium and Project Orbis. Please feel free to explore the full list with filters Country/Region [Singapore] and Document Type [Evaluation Summary].

Upcoming Training Sessions

Register for complimentary public training sessions

Date	Start Time	Session		Product	Actions
October 15, 2024	10:00 am CET/CEST (PARIS TIME)	Cortellis Regulatory Intelligence essentials - Understand the global and local regulatory landscape (45 min+Q&A)	English Live	Cortellis Regulatory Intelligence	Register
October 17, 2024	12:00 pm EST/EDT (NEW YORK TIME)	Cortellis Regulatory Intelligence essentials - Understand the global and local regulatory landscape (45 min+Q&A)	English Live	Cortellis Regulatory Intelligence	Register

Country/Region

Click the links to go to new and updated documents for each country

International							
Africa - Middle East							
Algeria	Egypt	Gulf Cooperation Council	Iraq	Israel	Jordan	Kenya	Lebanon
Morocco	Nigeria	Saudi Arabia (1)	South Africa	Tunisia	United Arab Emirates		
Asia Pacific							
ASEAN (2)	Australia (1)	China (1)	Hong Kong	India	Indonesia	Japan (1)	Malaysia
New Zealand	Philippines	Singapore	South Korea (1)	Taiwan (1)	Thailand	Vietnam	
Europe							
Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic (1)	Denmark	EAEU
Estonia	European Union (6)	Finland	France (1)	Germany	Greece	Hungary	Iceland
Ireland	Italy	Latvia	Lithuania	Luxembourg	Malta	Netherlands	Norway
Poland	Portugal	Romania	Russian Federation	Serbia	Slovakia (2)	Slovenia	Spain
Sweden	Switzerland	Turkey	Ukraine	United Kingdom			
Latin America							
Argentina	Brazil (1)	Chile	Colombia	Costa Rica	Guatemala	MERCOSUR	Mexico
Panama	Peru	SICA	Venezuela				
North America							
Canada	USA (5)						

Weekly Update

Click the links to jump to each report type for the country/region

European Union (6)

Regulatory Intelligence Reports (4) | Approval Tracker (2) | Product Approval (1) | Public Comment (1) | Reference Documents (2) | Announcement (1) | EPAR (1)

Risk Management System Tracker

Click the report titles to open the reports in Cortellis

200272 Drugs and Biologics Regulatory Intelligence Report

This Regulatory Intelligence Report (RIR) provides summary of Risk Management Plan information as well as additional monitoring status for new products approved in centralized procedure and submitted with a Risk Management Plan (RMP). The reason(s) and the date of inclusion in the list of additional monitoring are provided. Summary of safety concerns are outlined, covering important identified risks, important potential risks and/or missing information. Additional risk minimisation measures (RMIM) are also detailed: risk(s) concerned, type, description and rationale for RMIM.

Since July 2012, all new marketing authorisations (MAs) applications should include an RMP. However, as the provision of an RMP was not mandatory before that date, there are still MAs for some centrally authorised products without an RMP. For these products without RMP, certain situations (such as new safety concerns, or significant changes to the MA) may trigger the need to introduce an RMP.

Please note that the publication of RMP summaries in the format used during the pilot phase ceased for new medicines which received a CHMP opinion from January 2016 onwards. When the Summary of the RMP is not available as individual document in the EPAR, then data are taken from the 'Scientific Discussion' section of the EPAR.

Reason For Update:

This is updated to include any new and updated content related to the Risk Management System Tracker Intelligence Report

Last Updated Date: 23-Sep-2024

Regulatory Version: None

Click the links to navigate through the Weekly Update

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EU Medicinal Products Registration Overview

154019 Drugs and Biologics Regulatory Intelligence Report Approval Tracker Product Assessment English

This Regulatory Intelligence Report (RIR) provides a list of all centralized products approved since their first EPAR, and products withdrawn and suspended. 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 Use" 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.

Reason For Update:

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

Last Updated Date: 23-Sep-2024

Regulatory Version: None

Read the abstracts to understand what the report is about before opening the documents to explore further.

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Viewing previous and Excel versions

Back in the Cortellis platform, hover over your name in the upper right corner and select Weekly Updates. Then select the version from the tabs at the top.

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Reports
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Side by side History









Weekly Updates

Drugs and Biologics

Medical Devices and IVDs

Drugs and Biologics & Medical Devices and IVDs

Click the icons to view the HTML or Excel versions

Volume	Date ↓	My Preferences	Actions
Volume 11	11-Mar-2024	Country / Region: US; China; Document Categories: Regulatory Intelligence Report; Regulatory Summary; Document Types: Federal Register Announcement; Inspection Report; Public Comment; Regulation;	 
Volume 10	4-Mar-2024	Country / Region: US; China; Document Categories: Regulatory Intelligence Report; Regulatory Summary; Document Types: Federal Register Announcement; Inspection Report; Public Comment; Regulation;	 
Volume 9	26-Feb-2024	Country / Region: US; China; Document Categories: Regulatory Intelligence Report; Regulatory Summary; Document Types: Federal Register Announcement; Inspection Report; Public Comment; Regulation;	 
Volume 8	19-Feb-2024	Country / Region: US; China; Document Categories: Regulatory Intelligence Report; Regulatory Summary; Document Types: Federal Register Announcement; Inspection Report; Public Comment; Regulation;	 

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