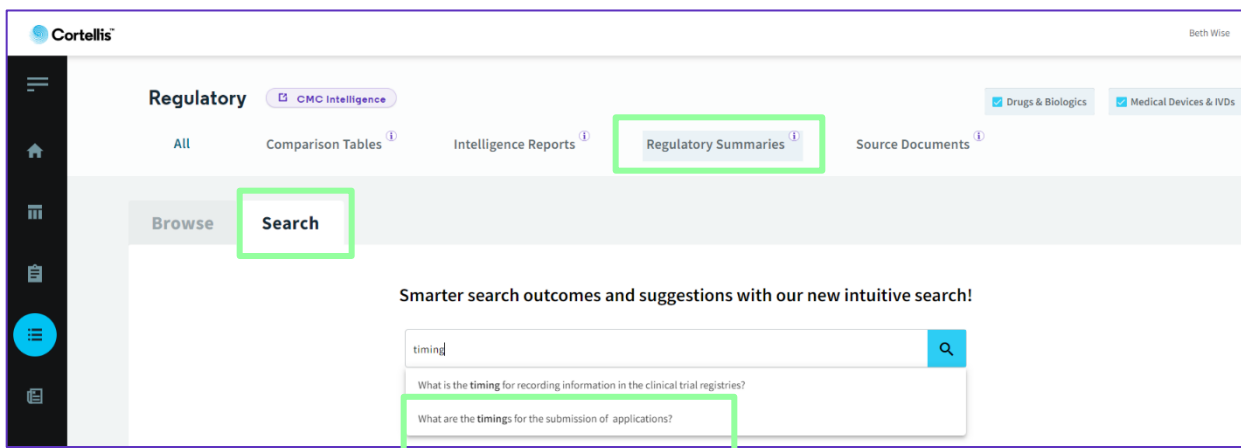


Better results with intuitive search

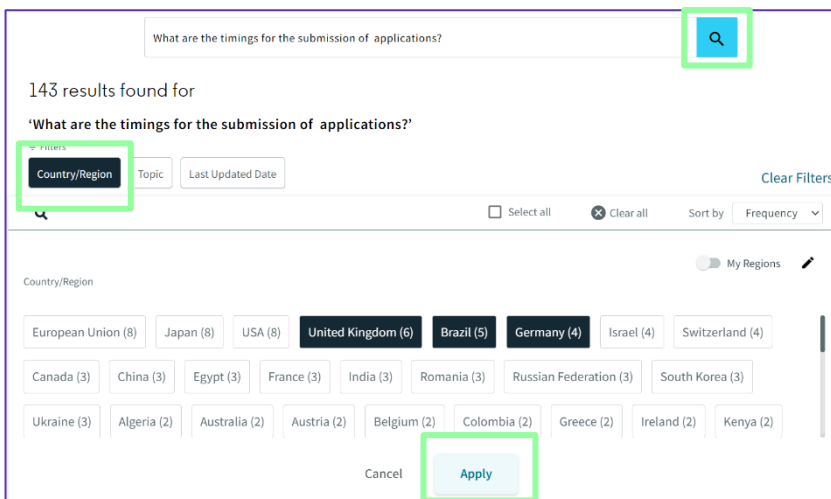
Compare answers to common regulatory questions across countries and regions within the Regulatory Summaries and easily search the Regulatory Intelligence reports with the new intuitive search in Cortellis Regulatory Intelligence.

Example: View timings for the submission of Marketing Authorization Applications in Spain, Germany, the UK, Brazil and Argentina.

1. Click the Regulatory Summaries tab
2. Select Search
3. Begin typing keywords from your question into the box, for example *timing*
4. Select a question from those appearing in the drop down menu



5. Use the filters to narrow down your results. For example, use the Country/Region filter to narrow down to just Spain, Germany, the UK, Brazil and Argentina
6. Click Apply, followed by the blue search icon next to the search box in order to refine



14 results found for

'What are the timings for the submission of applications?'

Filters

Country/Region Topic Last Updated Date

Sorted by Relevance

Expand All Collapse All

7. Select “Expand All” and scroll to compare the answers to your question country by country in the results.

Summary

- 03-Sep-2021 V

SP EN RS

Marketing Authorization Procedures: Review, Communication and Approval

This document provides the principal marketing authorization application stages through the national procedure.

Country/Region: Spain
IDRAC Number: 229
Last Updated Date: 03-Sep-2021

What are the timings for the submission of applications?

According to the regulation Royal Decree 1345/2007 , the maximum time limit to obtain the authorization is 210 calendar days from the reception of a dossier considered as complete. The clock is stopped when the Authorities request additional information.
- 02-Aug-2021 V

DE EN RS

Marketing Authorization Procedures: Review, Communication and Approval

This document provides the principal marketing authorization application stages through the national procedure.

Country/Region: Germany
IDRAC Number: 311
Last Updated Date: 02-Aug-2021

What are the timings for the submission of applications?

1. Applications to BfArM For national marketing authorization applications, the agency does not necessarily have to be notified in advance, the application can be submitted at any time. For MRP procedures, there is no need for a slot request, prior notification is however recommended, especially if an MRP procedure with Germany acting as RMS is planned. An informal application to the process management of the licensing unit should be sent well in advance. For DCP procedures where the BfArM is planned as RMS, applications can be submitted without a slot request and can be started after validation of the application. However, to support internal planning, BfArM is asking that even in cases where slot requests are not required, information with regard to a planned submission is e-mailed to slotrequest-DCP@bfarm.de at least 3 months in advance. However advance slot requests are still required for products with certain ATC codes for which the BfArM has published a list in their BfArM information on slot requests. For products with these ATC codes, the slot request must be e-mailed to slotrequest-DCP@bfarm.de and contain the following information: E-mail request or cover letter including correct ATC code for the product and reference to the relevant licensing unit in BfArM (for ATC code assignment to licensing unit see Organization of BfArM; for herbal medicinal products the letters “PHY” and “HOM” are to be used instead of the ATC code. Completed HMA/CMD (h) request for RMS in a DCP form (<https://www.hma.eu/219.html>). A binding statement of the applicant's preferred submission date. Further information has been given by BfArM in their Allocation of Slots in the Decentralised Procedure (DCP) at BfArM guidance document. A few days after receipt of the request, BfArM will respond and propose a slot which the applicant has to confirm or decline within 3 days. 2. Applications to PEI The PEI has not published information on slot requests. Purely national applications can be submitted at any time. For MRP or DCP procedures where the PEI is planned as RMS, a specific procedure has not been defined. It is recommended to contact the relevant PEI licensing unit to discuss the request well in advance (commonly 3 months in advance).
- 28-Sep-2021 V

AR EN RS

Marketing Authorization Procedures: Review, Communication and Approval

This document provides detailed, practical information and flow charts about the national authority review process, for the type of products detailed below: - Article 3 and 5 products (see Definitions in Decree 150/92), - Article 4 products (see Definitions in Decree 150/92), - Biological and biosimilar products.

Country/Region: Argentina
IDRAC Number: 26800
Last Updated Date: 28-Sep-2021

What are the timings for the submission of applications?

The normative do not describe timelines for submission.
- 06-Sep-2021 V

BR EN RS

Marketing Authorization Procedures: Review, Communication and Approval

This document provides an overview of the principal marketing authorization application stages as well as detailed information about the review process of each major category of product in Brazil. It includes comprehensive, practical information about the national authority review, communication and approval process.

Country/Region: Brazil
IDRAC Number: 25629

For more information contact Customer Service at [LS Product Support](#).