

Regulatory Intelligence: Comparisons Tables in Cortellis

The Comparison Tables in Cortellis provide a single access point of content, regulatory expertise and visual enhancements to quickly identify common and divergent requirements across multiple countries and regions on a topic.

- Once you have logged in, you can access Comparisons Tables from the CRI Home Page. Click the Comparison Tables tab to see a list of available topics. For this example, only Drugs and Biologics is chosen but you can also view Comparison Tables for Medical Devices & IVDs. Simply check the appropriate boxes. In the event you only have access to one type of content you will not see the other.

Regulatory

☒ Drugs & Biologics
 ☐ Medical Devices & IVDs

All

Comparison Tables

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Expand all
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- The Comparison Tables tab will display the comparisons subjects. Click the purple links to open the Comparison Table.

► Authorities and Organizations
Regulatory and Governmental Bodies
Transparency
► Legal Definitions and Marketing Requirements
Biosimilar Products
Generic Products
Pharmaceutical Laws and Regulations
Pharmacopoeias
► Format and Content of Applications
Common Technical Document (CTD) - electronic
Common Technical Document (eCTD) Acceptability
Stability Data and Conditions for Finished Products

► Marketing Authorization Procedures
Access to Unapproved Drugs
Change of Manufacturing Site (Finished Product)
Market Authorization Approval Expected Authority Review Times
► Fees
Pre- and Post-Approval Fees
► Product Information
Packaging - Labeling
► Clinical Research
Clinical Trial Application and Ethics Committee
Expected Authority Review Times
Clinical Trial Application: Local Requirements

► Quality Assurance
GXPs
► Pharmacovigilance and Risk Management
Post-Marketing Expedited Reporting
Post-Marketing Periodic Reporting
Pre-Marketing Expedited Reporting
Pre-Marketing Periodic Reporting
Risk Management and Qualified Person for Pharmacovigilance
► Import and Export
Certificate of Pharmaceutical Product

- By default, the Snapshot page will be displayed first. Title, last update, key subject section, abstract, IDRAC number and source are listed on the Snapshot page. To examine the Comparisons table, click on the Global Comparisons Tab.

Biosimilar Products	
Snapshot	Global Comparisons Change History
SNAPSHOT	
Title	Biosimilar Products
Last Update Date	21-Jan-2020
Section	Legal Definitions and Marketing Requirements
Abstract	<p>This subject presents the current legislative and/or regulatory framework related to biosimilar medicinal products worldwide. Because 'biosimilar' terminology varies across countries, this subject provides the local term and definition of biosimilar medicinal product as well as reference product to be used for the comparability exercise. These definitions are in English, as per official texts, or in the local national language by default.</p> <p>Abbreviations: ABN: Australia Biological Number; ANVISA: Agencia Nacional de Vigilancia Sanitaria (National Health Surveillance Agency); CDSCO: Central Drugs Standard Control Organization; DCGI: Drugs Controller General of India; EMEA: European Medicines Agency; EU: European Union; FDA: Food and Drug Administration; INN: International Nonproprietary Name; JAZMP: Javna Agencija Republike Slovenije za Zdravila in Medicinske Pripomočke (Agency for Medicinal Products and Medical Devices of the Republic of Slovenia); MoH: Ministry of Health; NBE: New Biological Entity; NCE: New Chemical Entity; SBMP: Similar Biological Medicinal Product; SFDA: Saudi Food and Drug Administration; TGA: Therapeutic Goods Administration; WHO: World Health Organization.</p>
IDRAC Number	109236
Product Category	Drugs and Biologics
Source	Cortellis RI


The comparisons are displayed in a matrix table. The first column is fixed and shows the countries and regions included in your subscription.


Biosimilar Products


Snapshot

Global Comparisons

Change History

My Regions 

ON 

Order Columns 

Country/Region	Legislative / Regulatory Framework Notes	Link to law or guideline	Definition of biosimilar	Definition of reference product	Exclusivity for 1st Biologic (in years)
Filters					
Argentina	Disposition 7729/2011 details the requirements applying to the registration of products of biologic origin having a similar profile than a reference product of biologic origin.	Disposition 7729/2011: Sets up the Requirements for the Marketing Authorization of Medicinal Products of Biological Origin Similar to Other Medicinal Products of Biological Origin Already ...	The term "biosimilar product" is not officially recognized and used in Argentina. A "similar product" is defined as: a product to be registered which is equivalent to other products approved and marketed either in Argentina ...	Reference Medicinal Product: medicinal product duly authorized by the Sanitary Agency whose efficacy and therapeutic safety have been scientifically proved by its clinical use and marketed in the country by an innovator ...	No information provided.
Brazil	The Brazilian legislation defining a pathway for biosimilars registration was introduced in December 2010. A simplified procedure has been introduced by Resolution RDC 31 of 29-May-2014 for generic and biosimilar ...	Resolution RDC 55: Sets Forth Provisions on the Requirements of New Biological Medicinal Products and Non Innovative Biological Medicinal Products' Registration, 16-Dec-2010 ...	ANVISA does not use the terminology "BIOSIMILAR" but uses the concept of Comparability: the scientific comparison between a biological product and a comparable biological product to prove that no detectable ...	Biological product already registered by the ANVISA on the base of a complete registration dossier and marketed in Brazil.	No market exclusivity. However, as for generics the reference product has to be out of patent.
Canada	Guideline available.	Questions & Answers to Accompany the Final Guidance for Sponsors Information and Submission Requirements for Subsequent Entry Biologics (SEBs), Updated 31-May-2010 ...	Biosimilar biologic drug (Médicament biologique biosimilaire): A biologic drug that obtains market authorization subsequent to a version previously authorized in Canada, and with demonstrated similarity to a ...	Reference biologic drug (Médicament biologique de référence): A biologic drug authorized on the basis of a complete quality, non-clinical, and clinical data package, to which a biosimilar is compared to demonstrate ...	Data exclusivity does apply to biosimilars in Canada, but only if the biosimilar is regarded as a New Molecular Entity. There appears to be a contradiction in thinking here because biosimilars are similar (very similar) to the ...

the column header and making your selections or turning on the My Regions Filter.

You can change the columns order and limit the display to countries and regions of interest by clicking on Filters located under the column header and making your selections or turning on the My Regions Filter.

Columns displayed vary depending on the topic. Columns called Regulatory Summary, Guideline or similar may include hyperlinks which provide access to deeper information. If you click on a link the underlying Regulatory Report will be displayed.

- The Change History section lists all updates and additions made to a Global Regulatory Comparison over time. You also have the option to **export** Global Regulatory Comparisons into Excel and **set up an alert** to get informed about changes automatically.

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Global Regulatory Comparisons Report
Alert Download

Biosimilar Products

Snapshot
Global Comparisons
Change History

CHANGE HISTORY

SUMMARY

Last Update Date

21-Jan-2020

Added Date

11-Jun-2010

CHANGE HISTORY DETAIL

Date	Country/Region	New/Updated	Section
21-Jan-2020	Switzerland	Updated	Link to law or guideline
23-Dec-2019	Hong Kong	Updated	Link to law or guideline
07-Nov-2019	Morocco	Updated	Legislative / Regulatory Framework Notes

Any alerts you set up in the desk top version of Cortellis are translatable to the **Cortellis Regulatory Intelligence App**. You can also view the tables in the App. Simply visit your device App store and search for “Cortellis” and download the app to your device. There is also a separate guide that walks you through how to download and set up the app.

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

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