USER'S MANUAL 2022

"Database For Caribbean Regulatory System"

CONSULTANCY FOR THE DEVELOPMENT OF AN ONLINE PRODUCT DATABASE FOR THE CARIBBEAN REGULATORY SYSTEM



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Introduction

The CARPHA Caribbean Regulatory System applies regulatory reliance approaches to conduct verification reviews of medical products that have been approved for market authorization by trusted regulatory authorities. This procedure aims to ensure sameness and to make recommendations for market authorization or procurement by Member States. This enables countries that lack national systems to identify quality products for procurement and enables those with national systems to use the recommendations to support market authorization decisions. In response to the pandemic, the CRS extended its work to the review of COVID-19 vaccines and medicines to assist Member States with market decisions for these products.

The identification of quality-assured medicines and vaccines enables Member States with established systems of medicines assessment to make faster decisions for market access than would be possible through traditional pathways. For CMS that lack a legislated system for the assessment and registration of medical products, whereby a process of approval of suppliers or approval of the importation of products exists, the CRS' work provides a key regulatory function. Towards greater transparency of information about medicines and vaccines recommended by the CRS to CARICOM, an online database will assist health administrators, regulators, health professionals, regulatory officers, members of the public, international development partners, health workers, procurement agencies, and the public to access information about the characteristics of products recommended by the CRS.

This user manual is a document provided to guide in using CARPHA Online Database. This manual covers detailed information about standards & guidelines, functionalities & more.

Users can access it through the following link <u>https://carpha.org/What-We-Do/CRS/Caribbean-</u> <u>Regulatory-System</u>

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Glossary

CRS Reference Number: The numerical code assigned to medical products recommended by the CRS

Non-Proprietary Name (also called the generic Name): The Name used to identify the pharmaceutical substances or active pharmaceutical ingredients in a medicine

Tradename (also known as the brand name): Refers to the commercial or proprietary Name assigned to the medical product by the pharmaceutical company or other legal entity that owns the product.

Market Authorization Holder: The company or other legal entity authorized to market a medical product in each country or region.

Active: Products registered by the CRS with a current recommendation

Conditional: Products registered by the CRS with valid recommendations with certain restrictions, e.g. For Pandemic Use

Suspended: Products registered by the CRS where the recommendation has been suspended

Withdrawn: Products registered by the CRS where the recommendation has been withdrawn, voluntarily or based on the product standing set by the reference authority

Expired: Products registered by the CRS where the recommendation has expired.

General Overview



Once users go to CARPHA'S website, they will see the option in the image below

Figure 1: View of CRS Home Page.

Search Options

You may search for a registered product by its: CRS Reference Number, Non-proprietary Name, Trade name, Market Authorization Holder, or Product type.

Select the type of search field you will use. Enter the number or name you are searching for in the space provided as 'Search'. Select the product status from the options provided: All, Active, Conditional, Withdrawn, Expired, Suspended.

SIMPLE SEARCH:

The user will click on CRS Online Database, and the System will deploy the following:

In the first part, a simple search engine allows one to search by two parameters. After that, users will have a screen where they can choose the filter, and they will have to complete the search box (Free Text).

Iccalhost:8080/CR5/public/ × +		~ - 0 X
← → C © localhost:8080/CRS/public/		N 🖄 🛧 🕨 🔮 :
	Select: CRS Reference number	
	Search: CR5/022017/H4001	
	Status: All	
	Canada Advanted Canada	
	and an and an	
	Copyright © 2022	

Figure 2: View of Search Page of Database.

On a simple search, you may search using: the CRS Reference Number, Non-Proprietary Name, Tradename, Market Authorization Holder, or Product Type.

	CRS Reference number	
Search:	Tradename	
Status:	Product Type	
	Search	Advanced Search

Figure 3: Search Filter.

After completing that information, a status filter is also available. In this case, the product's status should be defined; otherwise, the option "all" will be enabled by default.

Select:	CRS Reference number	×)
iearch:	CR5/022017/HA001	
štatus:	All	~
	All	
	Active	
	Withdrawn	
	Suspended	
	Conditional	

Figure 4: Status Filter.

• • • 6 When everything is completed click on search, and the results will show on the screen.

ADVANCED SEARCH

Advanced Search is also available to look up a product using multiple fields at the same time. The available filters are Trade Name, Product Type, Non-proprietary Name, and Market Authorisation Holder.

Steps for Advanced Searches:

When the User clicks on Advanced Search, the options of the filters' combinations appear, which are: Trade name, product type, non-proprietary name, and market authorization holder, once selected the text field appears automatically, and it is mandatory to fill it out; the search will take place with a combination of both parameters.



Figure 5: Advance Search.

SEARCH RESULTS

Regardless type of search performed (Simple or Advanced), a table with all the results that meet the criteria will be shown. In addition, the data table will contain the minimum information required to select the correct option when clicking on the <u>"Select"</u> button; and detailed information will display. Use the <u>'Select'</u> button to view the information for the relevant product.

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		s	elect:	CRS Refe	rence number			~						
		S	earch:	CRS/0220	17/HA001									
		s	atus:	All				~						
				-	Search	Advanced	Search							
							V-ADD							
	Show 10 V	entries												
	Show 10 V CRS Reference No.	Non-proprietary name	Trade N	Name	Market Authorization Holder	Date Issued	Status	Product Type	Option					
	Show 10 V CRS Reference No.	Non-proprietary name Lamivudine, Zidovudine	Trade N	Name	Market Authorization Holder Strides Shasun Ltd	Date Issued 2017-04-20	Status Expired	Product Type medicine	Option Select					
	Show 10 CRS Reference No. CRS/022017/HA001	ntries Non-proprietary name Lamivudine, Zidovudine tries	Trade N	Name	Market Authorization Holder Strides Shasun Ltd	Date Issued 2017-04-20	Status Expired	Product Type medicine	Option Select Previous	1	Next			
	Show 10 CRS Reference No. CRS/022017/HA001 CRS/022017/HA001 Showing 1 to 1 of 1 ent	Non-proprietary name Laminudine, Zidovudine tries	Trade N	Name	Market Authorization Holder Strides Shasun Ltd	Date Issued	Status Expired	Product Type medicine	Coption Select Previous	1	Next			
	Show 10 CRS/Reference No. 1 CRS/REFERENCE No. 1 CRS/022017/HA001 Showing 1 to 1 of 1 en	ntries Non-proprietary name Lamixudine, Zidovudine tries	Trade N	Name	Market Authorization Holder Strides Shasun Itd	Date Issued	Status Expired	Product Type medicine	Option Select Previous	1	Next			
	Show 0 CRS Reference No. CRS/022017/HA001 CRS/022017/HA001 Showing 1 to 1 of 1 em	ntries Non-proprietary name Lamixudine, Zidovudine tries	Trade N	Name	Market Authorization Holder Strides Shasun Ltd	2017-04-20	Status Expired	Product Type medicine	Option Select Previous	1	Next			
	Show 0 CRS Reference No. CRS/022017/HA001 CRS/022017/HA001 Showing 1 to 1 of 1 em	nnnes Non-proprietary name Lamixudine, Zidovudine tries	Trade N	Name 2	Market Authorization Holder Strides Shasun Ltd	2017-04-20	Status Expired	Product Type medicine	Coption Select Previous	1	Next			
	Show 0 CRS Reference No. CRS/022017/HA001 Showing 1 to 1 of 1 em	nnnes Non-proprietary name Lamixudine, Zidovudine trifes	Trade N	Name	Market Authorization Holder Strides Shasun Ltd	Date Issued 2017-04-20	Status Expired	Product Type medicine	Option Select Previous	1	Next			
	Show 10 CKS Reference No. 1 CKS Reference No. 1 CRS/022017/H4001 Showing 1 to 1 of 1 en	ntrites Non-proprietary name Lamixudine, Zidovudine trites	Trade N	Name	Market Authorization Holder Strides Shasun Ltd	Date Issued 2017-04-20	Status Expired	Product Type medicine	Coption Select Previous	1	Next			

Figure 6: Search result.

Product Information

To view the different sections of the product information, select the relevant tab from the list below:

- 1. General information
- 2. Manufacturing
- **3.** Product information.

General Information

The General Information tab will present the CRS Reference Number, product names (non-proprietary, trade name), Market authorization holder name, Regulatory Authority of Reference, Status, Recommendation dates, and where available, copies of the Summary of Product Characteristics, Patient Information Leaflet, and product images.

General Information Manufac	Product Information	
CRS Reference Number	CRS-062017-HA013	
Non-proprietary name	Abacavir	
Dosage form, strength	tablets, 300mg	and the second second second second
Trade name		
Market authorization holder	Strides Shasun Ltd	Not the second stability associations: 60 Tables / Days
Reference authority	World Health Organization Prequalification (PQ)	Alter and the second state of the projection. Abacant,
URL	https://extranet.who.int/pqweb/	the set of
Status	Active	The is some of a proceeding of the proceeding of the solution
Date Issued	2017-09-25	erent and and an and and and and and and and
Valid Until	24/9/2022	
Summary of Product Characteristics		
Patient Information Leaflet		Printable Version

Figure 7: General Information Tab

Manufacturing:

The manufacturer's tab will display in a table, showing the names and locations of manufacturers of the Active Ingredient(s) and Finished Product. Some products may have multiple manufacturers.

General Information Man	ufacturing	Product Information			
			Active Ingredie	nt Manufacturer	
Name of API manufacturer				Address	Country
ST Pharma Co. Ltd.					Korea
AMPAC Fine Chemicals LLC					United States
Cambrex Charles City					United States
Fabbrica Italiana Sintetici S.p.	A. (F.I.S.)				Italy
Gilead Sciences, Inc.					United States
Yuhan Chemical, Inc.					South Korea
F.I.S. Fabbrica Italiana Sintetic	i S.p.A.				Italy
Gilead Alberta, ULC					Canada
Hovione FarmaCiencia, S.A.					Portugal
Hovione Limited					Ireland
Esteve Quimica S.A.					Spain
PPD Development LP					United States

Figure 8: Active Ingredient Manufacturer List (Manufacturing Tab)

Finished Product Manufacturer

Name of FPP manufacturer	Address	Country
Gilead Sciences Ireland	UCIDA Business and Technology ParkCarrigtohill, Co. Cork	Ireland
Patheon Inc.	2100 Syntex CourtMississauga, Ontario Canada L5N 7K9;	Canada
PPD Development, LP	8551 Research Way, Suite 90Middleton, WI 53562-4663	United States
Gilead Sciences, Inc.	333 Lakeside DriveFoster City, CA 94404	United States
Gilead Sciences, Inc.	650 Cliffside DriveSan Dimas, CA 91773	United States
AndersonBrecon, Inc.	(PCI)4545 Assembly DriveRockford, IL 61109	United States
Millmount Healthcare Ltd.	Block-7, City North Business Campus, Stamullen, Co. Meath, K32 YD60	Ireland

Figure 9: Finished Product Manufacturer List

Product Information

The last tab contains information about the product, such as recommended indications, storage conditions, shelf-life, packaging, and additional aspects of note.

Showing 1 to 1	of 1 entries	Previous	1	Next
General Informatio	n Manufacturing Product Information			
Indications	Indicated for treatment of HIV-1 infection in adults and adolescents from 10 years of age and weighing at least 35kg			
Packaging	High-density polyethylene bottle containing 28 tablets.			
	High-density polyethylene bottle containing 30 tablets.			
	High-density polyethylene bottle containing 84 tablets.			
	High-density polyethylene bottle containing 90 tablets.			
Storage conditions	Store below 25°C. Keep in tightly closed container			
Shelf-life	24 months			
Notes				

Figure 9: Product Information Tab

There are links to PDFs of the Summary of Product Characteristics (SMPC/SPC) & Patient Information Leaflet (when available), which will be downloadable.

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	WIIO-PQ RECOMMENDED SUMMARY OF PRODUCT CHARACTERISTICS			PATIEST INFORMATION LEAVET	
	The annuary of product characteristics ficance on area of the medicine covered by #ID Proceediments from - Medicine. The proceediment for on one bood on WH2 without	25			

Figure 10: PDF of Summary of Product Characteristics (SMPC/SPC) & Patient Information Leaflet

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Printable Information

General Information Manufacturin	g Product Information	
CRS Reference Number	CRS-119-621-41	
Non-proprietary name	Meropenem USP	
Dosage form, strength	injection, 1000 mg	
Trade name		
Market authorization holder	Venus Remedies Limited	MEROPENEM
Reference authority	National Institute of Surveillance of Medicines and Food, (INVIN	
URL		
Status	Active	
Date Issued	2019-03-19	
Valid Until	18/3/2024	Richtle Marine
Summary of Product Characteristics	Not Available	Printable version
Patient Information Leaflet	Not Available	

On the General Information Tab, users will find a "Printable Version" Button

Figure 10: Printable Version Button

When you click on the button a PDF is generated with the Product Summary, users will be able to download or printed

=	CRS_022017_HA001.pdf	1/2 -	100% + 🖸 🚸	± 6 i
		CARIBBEAN PUBLIC HEALT	HAGENCY - CARIBBEAN REGULATORY SYSTEM	
		PRODUCT SU	MMARY	
		This product is recommended to approval, based on its assessm Would Health Organization, and	CARCOM for market authorization, emergency was authorization or import at by a national regulatory authority of reference, or propaillication by the subsequent verification by the Canabean Regulatory System.	
			GENERAL	
		CRS Reference Number	CRS/022017/ILA601	
		Non-proprietary Name	Lamivudine, Zidovudine	
		Dosage Form, Strength	tablets, 150mg/300mg	
		Trade Name		
		Market Authorization Holder	Strides Shasun L4d	
		Reference Authority	World Health Organization	
		Status	Expired	
		Date Issued	2017-04-20	
		Valid Until	2022-04-19	
			MANUFACTURING	
		Activa Ingrediant		

Figure 11: Product Summary PDF

https://carpha.org/