USER'S MANUAL 2022

"Database For Caribbean Regulatory System"

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

NOVEMBER 2022

Consultant: Ana Marcela Orellana

Caribbean Public Health Agency
CARPHA

Contents

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 https://carpha.org/What-We-Do/CRS/Caribbean-Regulatory-System

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

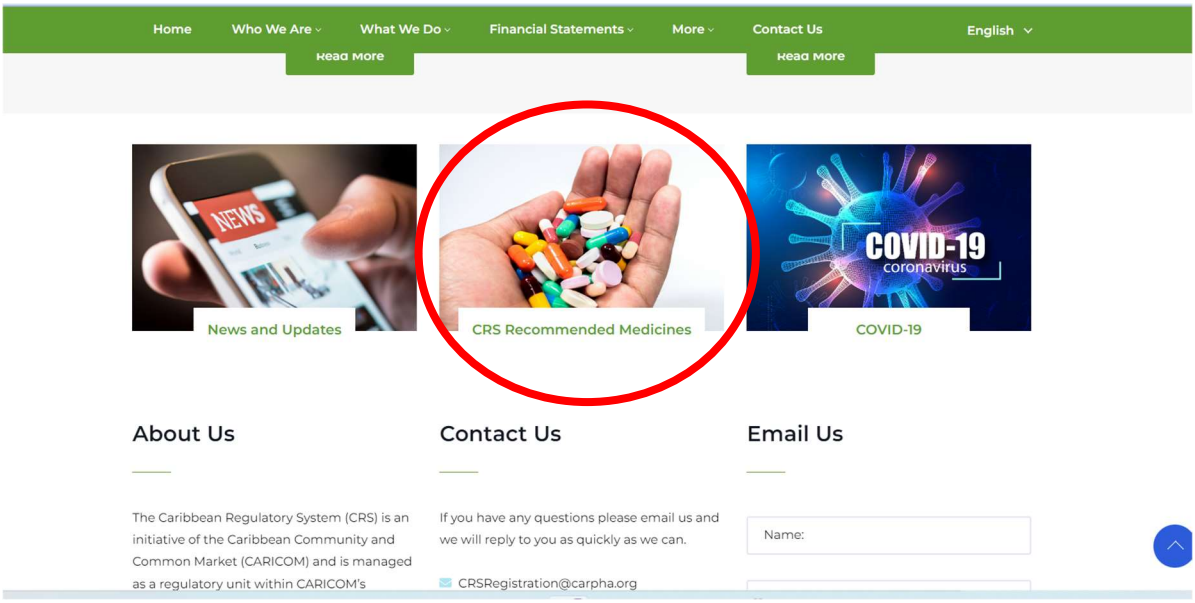


Figure 1: View of CRS Home Page.

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).

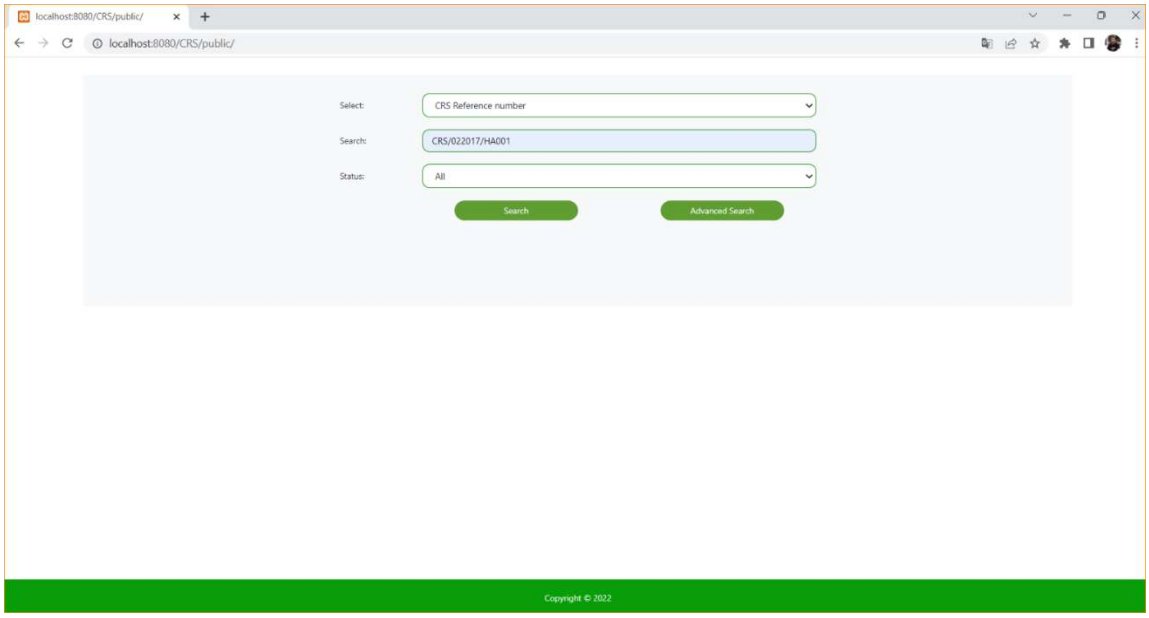


Figure 2: View of Search Page of Database.

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

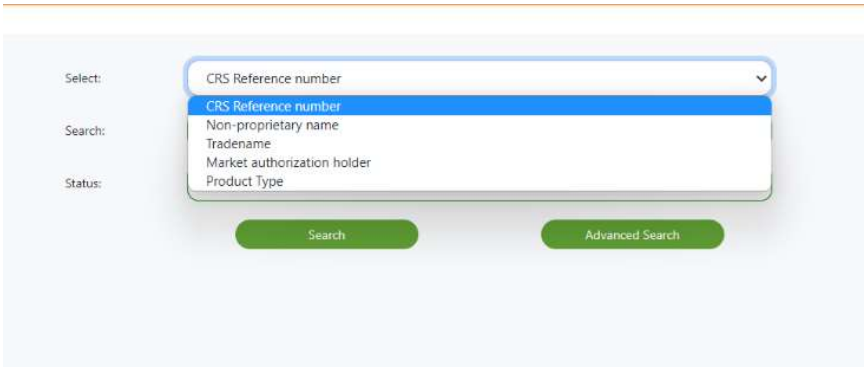


Figure 3: Search Filter.

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.

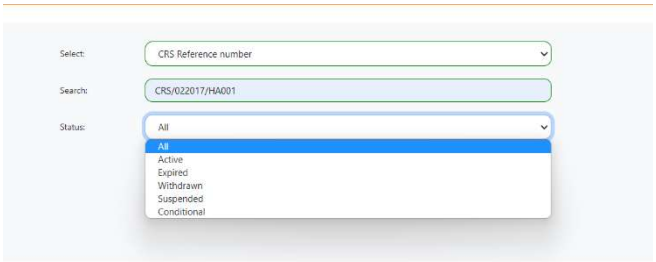


Figure 4: Status Filter.

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.

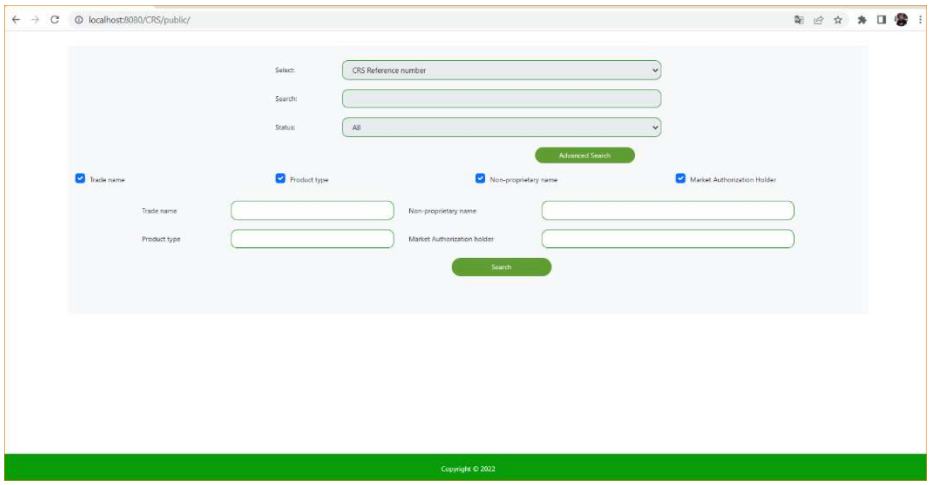


Figure 5: Advance Search.

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 **"Select"** button; and detailed information will display. Use the '**Select'** button to view the information for the relevant product.

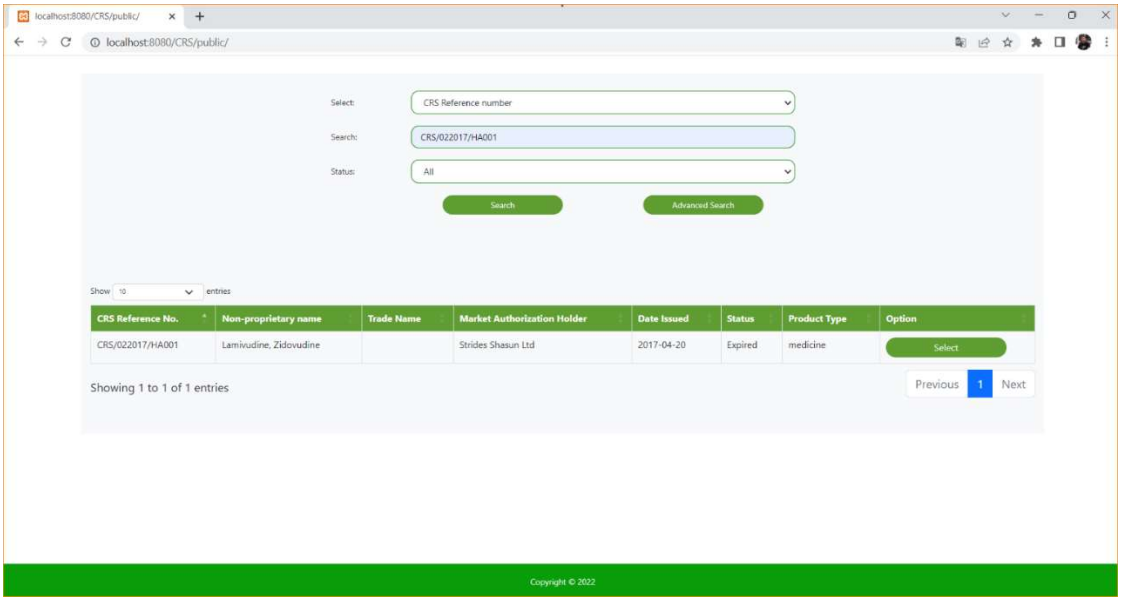


Figure 6: Search result.

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.

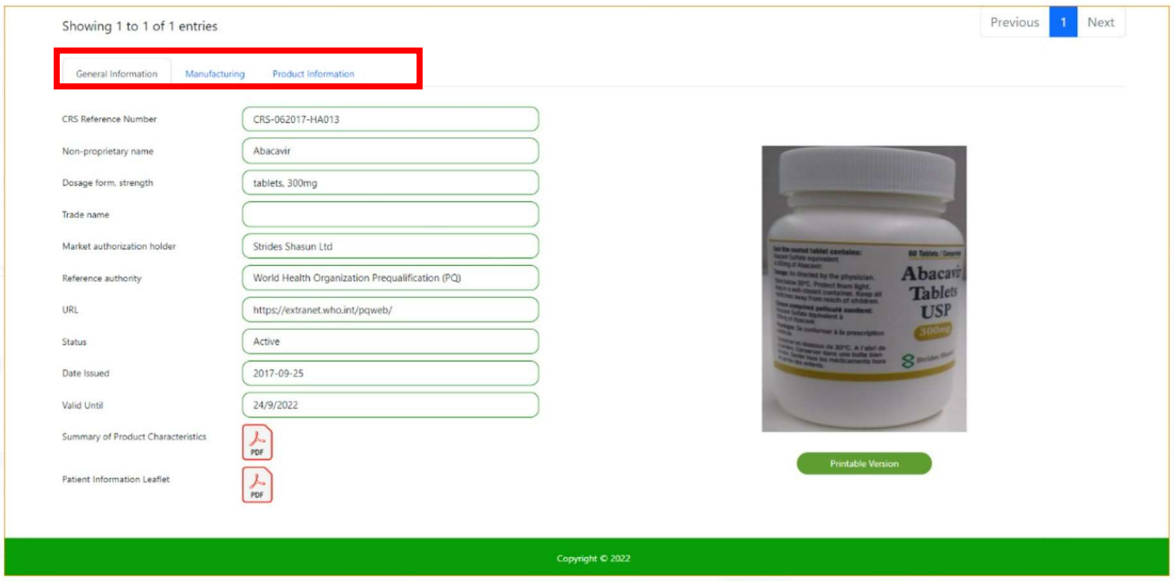


Figure 7: General Information Tab

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.

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 Sintetici 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.

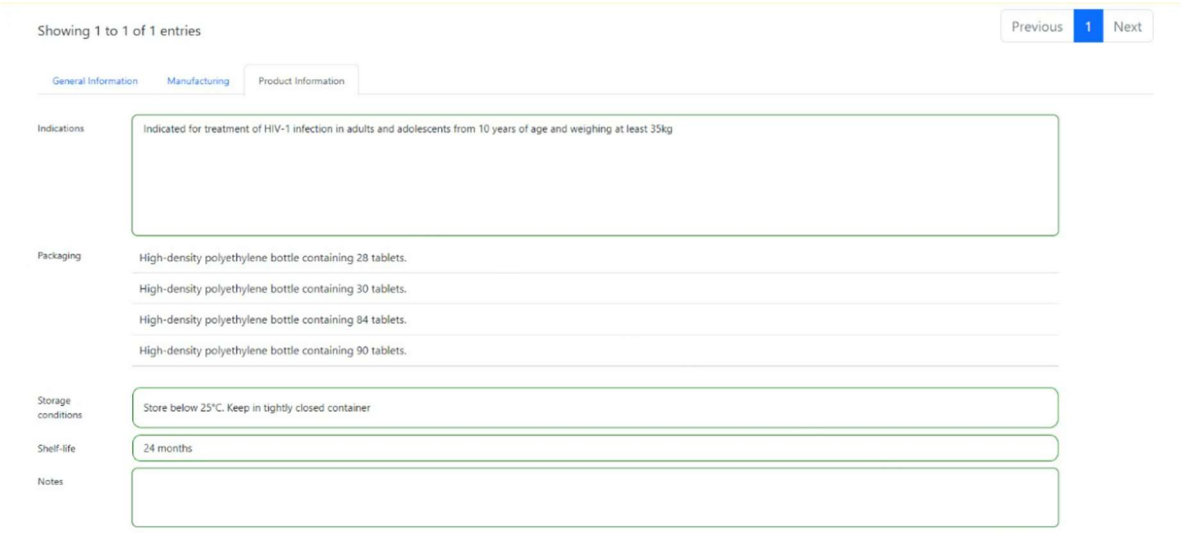
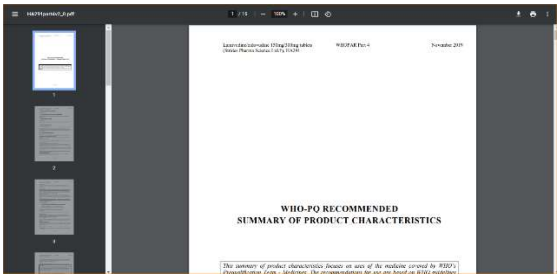


Figure 9: Product Information Tab

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



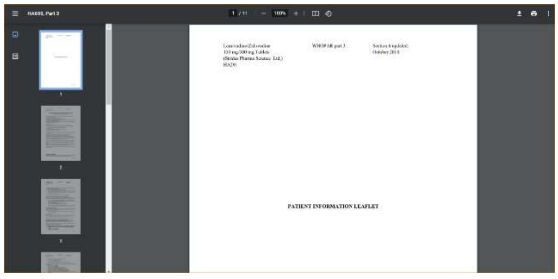


Figure 10: PDF of Summary of Product Characteristics (SMPC/SPC) & Patient Information Leaflet

Printable Information

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

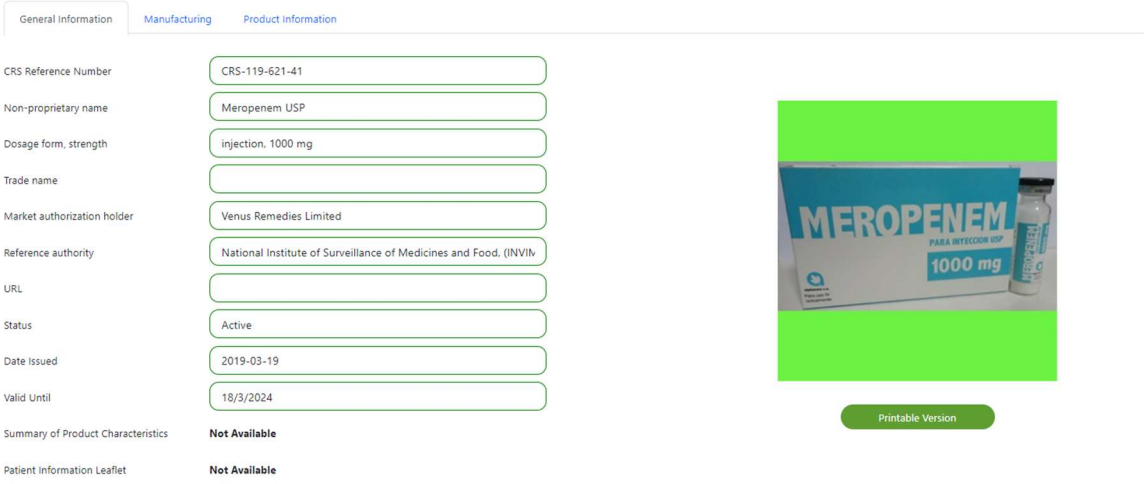


Figure 10: Printable Version Button

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

Figure 11: Product Summary PDF

https://carpha.org/