

INFORMASI CARA PENELUSURAN OBAT KOMPARATOR

Cara melakukan penelusuran obat komparator dilakukan sebagai berikut:

- A. Penelusuran Obat Komparator yang Terdaftar di Dalam Negeri
- B. Penelusuran Obat Komparator di Negara Lain

A. Penelusuran Obat Komparator yang Terdaftar di Dalam Negeri

1. Melakukan penelusuran obat komparator yang dengan cara masuk ke dalam web portal Direktorat Registrasi Obat Badan POM.
2. Dalam hal obat inovator sudah tidak ditemukan di seluruh dunia, maka dapat digunakan Obat Generik yang memenuhi kriteria bioekivalensi berdasarkan hasil kajian dari BPOM.
3. Apabila tidak ditemukan obat komparator pada data di PIONAS, maka dapat dilakukan dengan melakukan penelusuran obat komparator di luar negeri.

B. Penelusuran Obat Komparator di Luar Negeri

Penelusuran obat komparator di benua dan negara lain dapat melalui *website* berikut:

Benua	Website
Uni Eropa	https://tinyurl.com/search-EMA
Negara	Website
Amerika Serikat	https://tinyurl.com/searchFDA
United Kingdom	https://tinyurl.com/search-MHRA
Belanda	https://tinyurl.com/search-NLD
Jerman	https://tinyurl.com/search-DEU
Swiss	https://tinyurl.com/search-CHE
Polandia	https://tinyurl.com/search-RPL
Spaniol	https://tinyurl.com/search-CIMA
Perancis	https://tinyurl.com/search-ANSM
Austria	https://tinyurl.com/search-AGES
Jepang	https://tinyurl.com/search-PMDA
Singapura	https://tinyurl.com/search-HSA
Filipina	https://tinyurl.com/search-FDAPHL
Malaysia	https://tinyurl.com/search-NPRA

Setelah Saudara mencari dan menemukan obat inovator melalui penelusuran di negara lain, Saudara dapat melakukan klarifikasi hasil pencarian ke Direktorat Registrasi Obat Badan POM.

Adapun untuk obat komparator uji bioekivalensi, Saudara dapat mengirimkan hasil pencarian dan penelusuran Saudara berdasarkan tahap-tahap di atas melalui email penilaian.ujibe@pom.go.id.

Untuk komparator UDT, Saudara dapat juga melakukan langkah-langkah seperti pencarian komparator uji BE dan dapat mengirimkan hasil pencarian dan penelusuran Saudara untuk diklarifikasi lebih lanjut pada *email corporate* Subkelompok Substansi Obat Generik Baru atau Variasi sesuai dengan pendaftaran registrasi yang dilakukan.

1) Penelusuran Obat Komparator yang Terdaftar di Amerika Serikat

1. Ketik alamat *website* sebagai berikut <https://tinyurl.com/searchFDA> pada *browser* Anda. Setelah terkoneksi, akan muncul tampilan *website* pencarian produk milik FDA seperti pada gambar di bawah:

The screenshot shows the FDA Orange Book homepage. At the top, there are links for Home, Food, Drugs, Medical Devices, Radiation-Emitting Products, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, and Tobacco Products. A search bar is at the top right. Below the header, a message states: "On March 23, 2020, FDA removed from the Orange Book the listings for "biological products" that have been approved in applications under section 505 of the FD&C Act because these products are no longer "listed drugs" (see section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009)." There is also a note about the mobile app: "We've updated our mobile app! Download Orange Book Express 2.0" with links to the App Store and Google Play.

Find Approved Drugs

Search by Proprietary Name, Active Ingredient or Application Number

Enter at least 3 characters Search

Search by Applicant (Company)

Search by Dosage Form (for example: TABLET)

2. Pada kotak **Search by Proprietary Name, Active Ingredient or Application Number**, ketikkan nama produk/ zat aktif /pendaftar yang akan dicari, lalu klik **Search**. Seperti misalnya pada contoh dibawah, akan mencari 'Feldene' lalu klik **Search**.

Selanjutnya akan muncul hasil pencarian seperti pada gambar dibawah ini

The screenshot shows the search results for 'Feldene' on the FDA Orange Book website. The search bar at the top contains 'Feldene'. The results table has columns: MR. Status, Active Ingredient, Proprietary Name, Appl. No., Dosage Form, Route, Strength, IE Code, RLD, RS, and Applicant Holder. Two entries are listed:

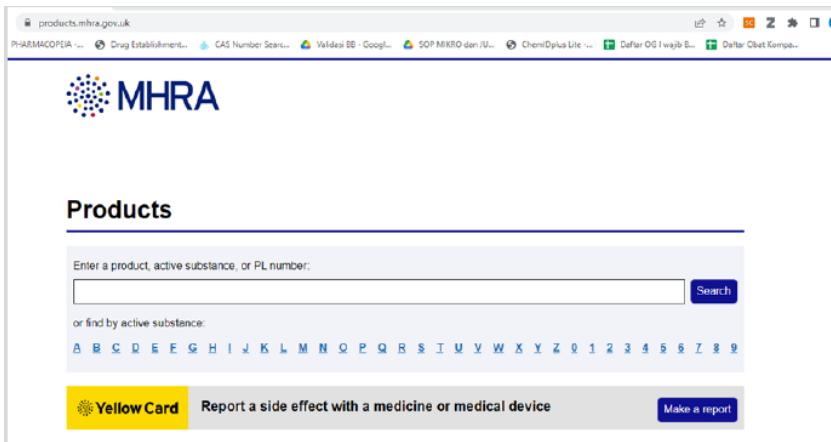
MR. Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	IE Code	RLD	RS	Applicant Holder
RX	PIROXICAM	FELDENE	N018147	CAPSULE	ORAL	10MG	AB	RLD		PFIZER LABORATORIES DIV PFIZER INC
RX	PIROXICAM	FELDENE	N018147	CAPSULE	ORAL	20MG	AB	BLD	RS	PFIZER LABORATORIES DIV PFIZER INC

At the bottom of the table, there are buttons for CSV, Excel, and Print. A note at the bottom of the page says: "Note: If you need help accessing information in different formats, see Instructions for Downloading Viewers and Players." It also lists language availability: English | Español | 简体中文 | 繁體中文 | English | Spanish | French | Italian | Portuguese | Bahasa | Deutsch | 日本語 | Русский | English.

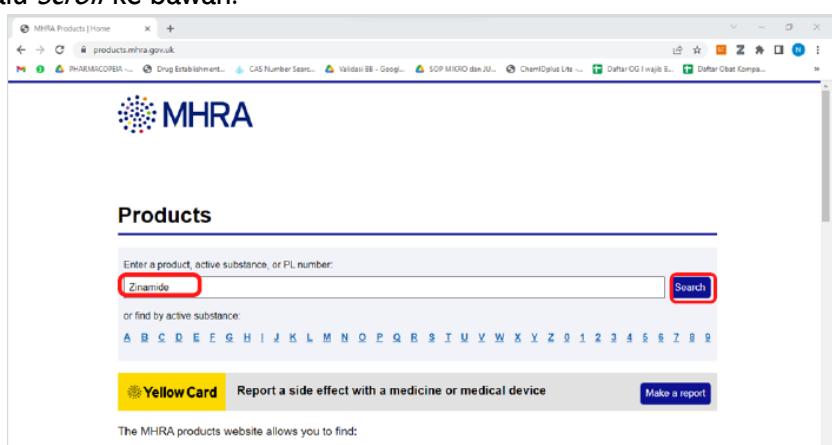
Dari hasil pencarian, *RLD (Reference List Drug)* mengindikasikan bahwa produk tersebut merupakan obat inovator. Sedangkan *RS (Reference Standard)* mengindikasikan bahwa produk tersebut telah ekivalen terhadap obat inovatornya.

2) Penelusuran obat komparator yang terdaftar di United Kingdom

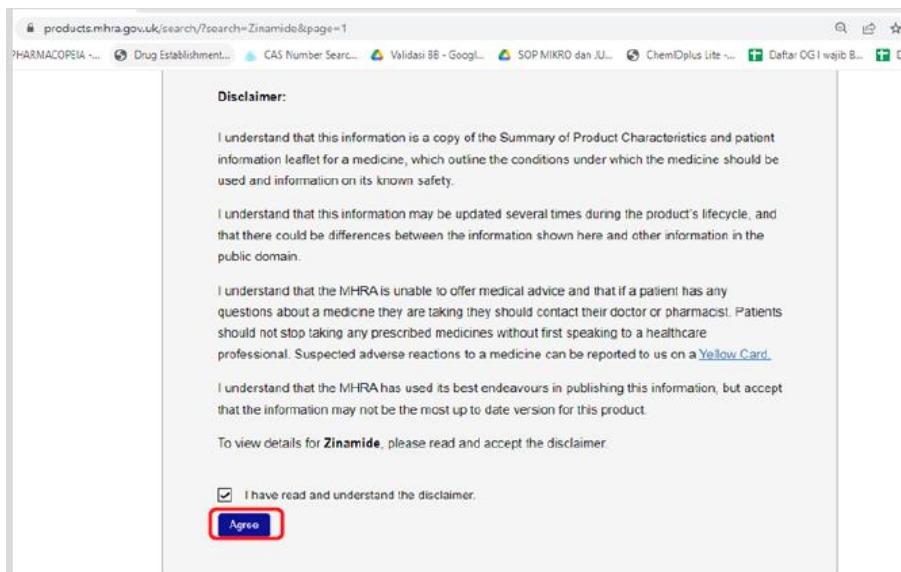
1. Ketik alamat website sebagai berikut <https://tinyurl.com/search-MHRA> pada browser Anda. Setelah terkoneksi, akan muncul tampilan website pencarian produk milik MHRA seperti pada gambar di bawah.



2. Pada kotak **Products**, ketikkan nama produk/ zat aktif/ nomor PL yang akan dicari, lalu klik **Search**. Seperti misalnya pada contoh di bawah, akan mencari 'Zinamide' lalu klik **Search**. Lalu scroll ke bawah.



Kemudian centang pada kotak '*I have read and understand the disclaimer*' lalu klik **Agree**.



3. Selanjutnya akan muncul hasil pencarian seperti pada gambar berikut:

Filter documents by

Type of document

- Summary of Product Characteristics (SPC)
- Patient Information Leaflet (PIL)
- Public Assessment Reports (PAR)

Applicable to territory

- United Kingdom (UK)
- Northern Ireland (NI)
- Great Britain (GB)

PIL **ZINAMIDE TABLETS 500MG**
Patient MAH BRAND_PL_06831-0206.pdf
File size: 68 KB
Active substances: PYRAZINAMIDE
Before you take **Zinamide** Tablets 500mg 3 ... How to take **Zinamide** Tablets 500mg 4 ... How to store **Zinamide** Tablets 500mg 6 ... WHAT **ZINAMIDE TABLETS 500MG ARE AND WHAT THEY ARE USED FOR** **Zinamide** Tablets 500mg contain pyrazinamide which is an...

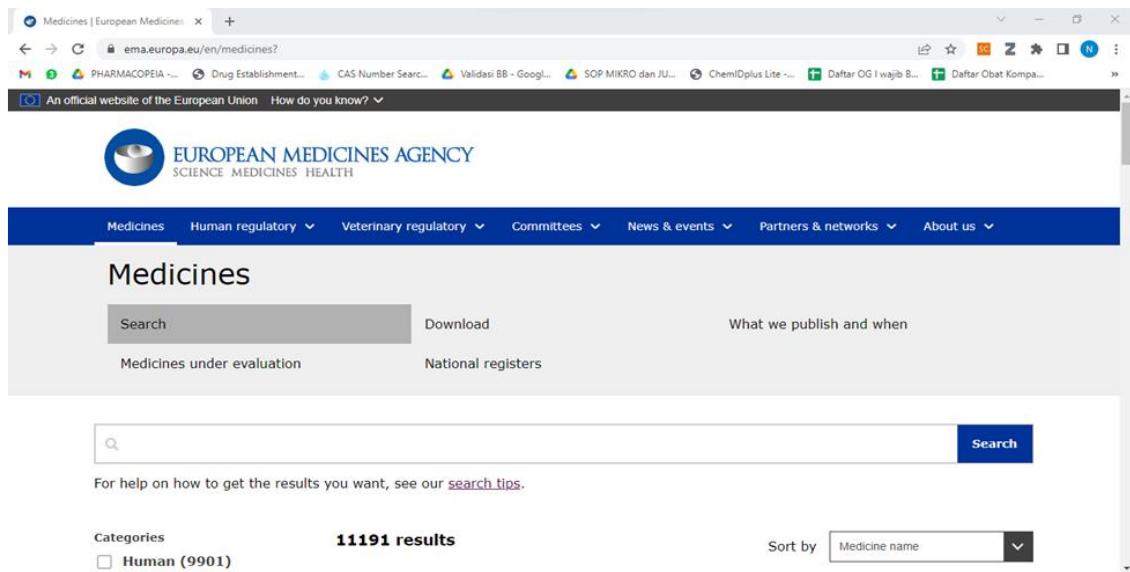
SPC **ZINAMIDE TABLETS 500MG**
spc-doc_PL_06831-0208.pdf
File size: 33 KB
Active substances: PYRAZINAMIDE
SUMMARY OF PRODUCT CHARACTERISTICS 1 NAME OF THE MEDICINAL PRODUCT **Zinamide** Tablets 500mg 2 QUALITATIVE AND QUANTITATIVE COMPOSITION Each tablet of **Zinamide** contains 500 mg of pyrazinamide Ph Eur ... Excipients with known effect Each tablet of...

PAR **pyrazinamide 500 mg tablets - PL 34771/0203 ; UK/H/6792/001/DC**
File size: 451 KB
This means that Pyrazinamide 500 mg tablets are similar to a reference medicine already authorised in the European Union called **Zinamide** Tablets 500mg ... Because Pyrazinamide 500 mg tablets is a generic medicine their possible side effects are taken as being the same as those of...

Hasil yang didapatkan dapat berupa **PIL** (*Patient Information Leaflet*), **SPC** (*Summary of Product Characteristics*) atau **PAR** (*Public Assessment Report*).

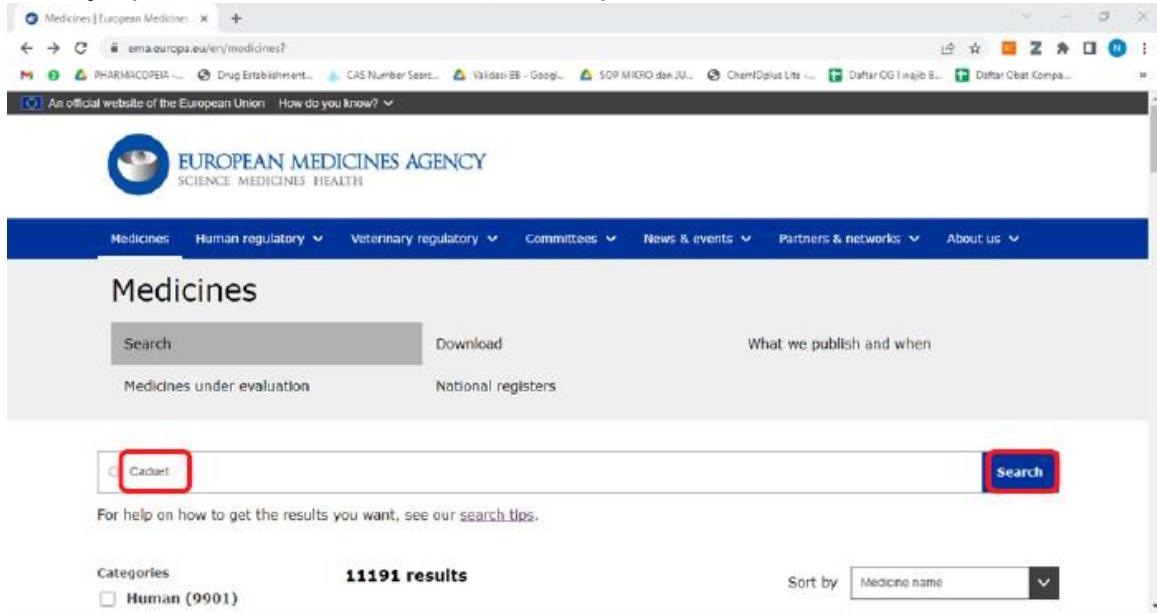
3) Penelusuran obat komparator yang terdaftar di Uni Eropa

1. Ketik alamat *website* sebagai berikut <https://tinyurl.com/search-EMA> pada *browser* Anda. Setelah terkoneksi, akan muncul tampilan *website* pencarian produk milik EMA seperti pada gambar



The screenshot shows the European Medicines Agency website. The top navigation bar includes links for Medicines, Human regulatory, Veterinary regulatory, Committees, News & events, Partners & networks, and About us. The main content area is titled 'Medicines' and features a search bar, a download link, and links for 'Medicines under evaluation' and 'National registers'. Below the search bar is a search tips link and a search results summary: 'Categories Human (9901) 11191 results Sort by Medicine name'. The search bar contains the text 'Search'.

2. Pada kotak pencarian ketikkan nama produk atau zat aktif yang akan dicari. Lalu klik **Search**. Misalnya, pada contoh di bawah, akan mencari produk 'Caduet' lalu klik **Search**.



The screenshot shows the European Medicines Agency website with a search query 'Caduet' entered into the search bar. The search bar is highlighted with a red box. The search results summary shows '11191 results' and 'Sort by Medicine name'. The search results page is not fully visible in the screenshot.

3. Hasil pencarian akan muncul seperti pada gambar di bawah ini

Screenshot of the European Medicines Agency (EMA) website search results for 'Caduet'.

Search results: 1 result found for 'Caduet'.

Key details from the result:

- Document: Amlodipine / atorvastatin: List of nationally authorised medicinal products - PSUSA/00000177/201601 (PDF/203.79 KB)
- Last updated: 19/10/2016
- Active substance: amlodipine, Atorvastatin
- Procedure number: PSUSA/00000177/201601
- Regulatory outcome: Maintenance

4. Kemudian klik tulisan *file PDF* untuk melihat produk tersebut terdaftar di negara Eropa mana saja. Dari dokumen PDF *List of nationally authorized medicinal products*, tekan Ctrl+F. Selanjutnya ketikkan nama produk yang akan dicari. Hasil pencarian akan muncul seperti pada gambar di bawah.

Screenshot of the European Medicines Agency (EMA) website showing the 'List of nationally authorised medicinal products' for 'Amlodipine / atorvastatin'.

Key details from the document header:

- Date: 29 September 2016
- EMA/662/66/2016
- Procedure Management and Committees Support

Section: List of nationally authorised medicinal products

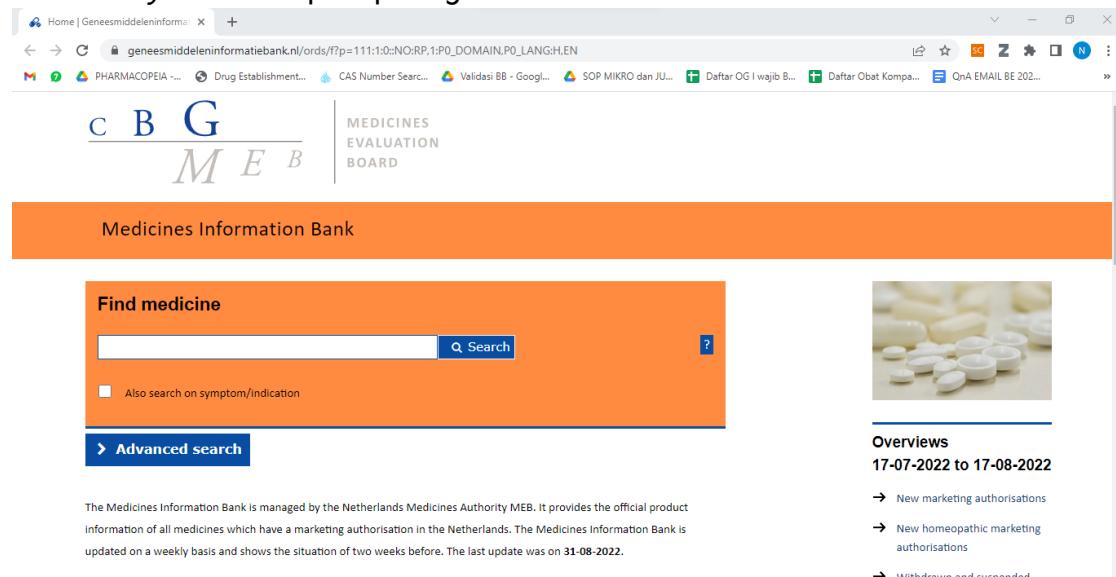
Active substance(s): amlodipine / atorvastatin

Procedure No.: PSUSA/00000177/201601

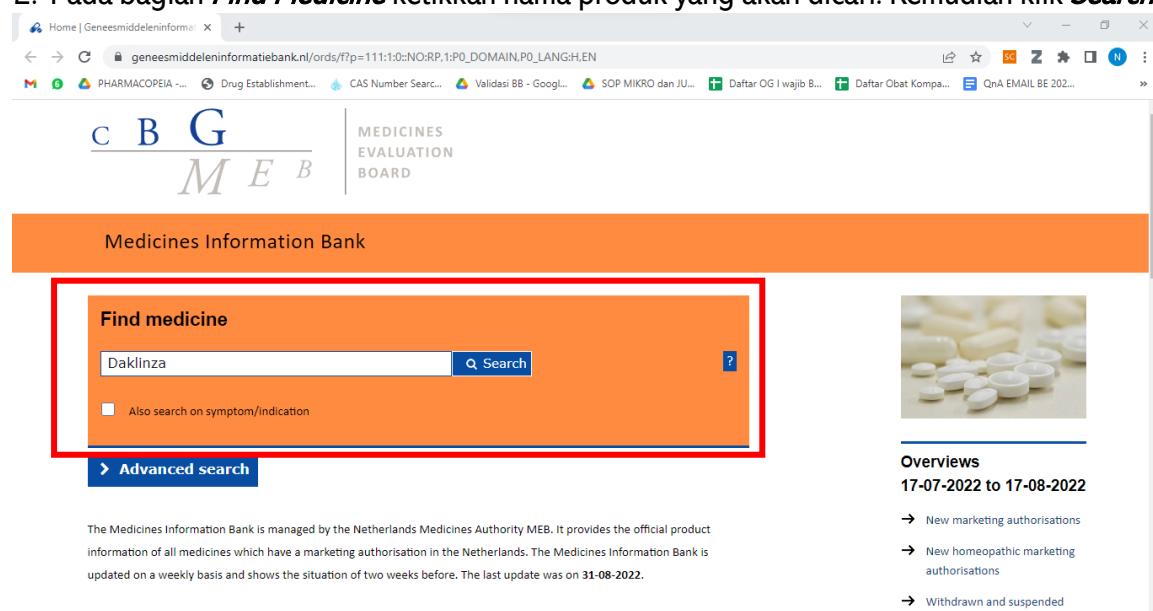
Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
		OGYI-T-22309/21 & OGYI-T-22309/22 & OGYI-T-22309/23 & OGYI-T-22309/24 & OGYI-T-22309/25 & OGYI-T-22309/26 & OGYI-T-22309/27 & OGYI-T-22309/28 & OGYI-T-22309/29 & OGYI-T-22309/30		
Atorvastatin/Amlodipine Teva	PT/H/1082/001 & PT/H/1082/002	LT/1/14/3620/003 & LT/1/14/3620/005	Teva Pharma B.V.	Lithuania
Atorvox Plus	PT/H/1082/001	22164	Teva Pharmaceuticals Polska Sp. Z O.O.	Poland
Atorvox Plus	PT/H/1082/002	22165	Teva Pharmaceuticals Polska Sp. Z O.O.	Poland
Azilodis	12/H/0086/001	5585120 & 5585138 & 5585146 & 5585153 & 5585161 & 5585179 & 5585203 & 5585211 & 5585229 & 5585237 & 5585245 & 5585252	Sigillata Limited	Portugal
Azilodis	12/H/0086/002	5584966 & 5584974 & 5585005 & 5585013 & 5585021 & 5585039 & 5585047 & 5585054 & 5585062 & 5585070 & 5585104 & 5585112	Sigillata Limited	Portugal
Caduet		6944/2006/01 & 6945/2006/01	Pfizer Europe Ma Eeig	Romania
Caduet		UP/1/530-09/11/02/295 & UP/1/530-09/11/02/296	Pfizer Croatia D.O.O.	Croatia
Caduet	FR/H/0280/001 & FR/H/0280/002	06-0020 & 06-0021	Pfizer Europe Ma Eeig	Latvia
Caduet	FR/H/0280/001 & FR/H/0280/002	1-26271 & 1-26273	Pfizer Corporation Austria Gesellschaft M.B.H.	Austria

4) Penelusuran Obat Komparator yang terdaftar di Belanda

1. Ketik alamat *website* sebagai berikut <https://tinyurl.com/search-NLD> pada *browser* Anda. Setelah terkoneksi, akan muncul tampilan *website* pencarian produk milik *regulatory authority* Belanda seperti pada gambar di bawah.



2. Pada bagian *Find Medicine* ketikkan nama produk yang akan dicari. Kemudian klik *Search*.



3. Selanjutnya akan muncul hasil pencarian seperti pada gambar berikut

Marketing authorisation number	Product name	ATC	Active substance
EU/1/14/939	Daklinza 30 mg filmomhulde tabletten	J05AX - Other Antivirals	DACLATASVIRDIHYDROCHLORIDE
EU/1/14/939	Daklinza 60 mg filmomhulde tabletten	J05AX - Other Antivirals	DACLATASVIRDIHYDROCHLORIDE
EU/1/14/939	Daklinza 90 mg filmomhulde tabletten	J05AP07 - Daclatasvir	DACLATASVIRDIHYDROCHLORIDE

1

5) Penelusuran obat komparator yang terdaftar di Jerman

1. Ketik alamat *website* sebagai berikut <https://tinyurl.com/search-DEU> pada *browser* anda. Setelah terkoneksi, akan muncul tampilan *website* pencarian produk milik *regulatory authority* negara Jerman. Pada bagian yang ditandai dengan warna merah, klik *English*, selanjutnya klik *research*

2. Pada bagian **Search For** ketikkan nama produk atau zat aktif yang akan dicari, lalu klik start **Search**.

Current module: Medicines

search for: [] Myambutol drug name: [] Myambutol

start search

limit search:

Admission Period: from [] until []

Marketable medicines: without restrictions only one

Human or veterinary medicinal products: without restrictions human veterinary medicines

parallel imports: without restriction Parallel import - applying application/authorization Approval referred to by the parallel import

Medicines only: Specialist information/instructions for use Public Assessment Reports (PAR) Risk Management Plans (RMP)

homeopathics: without restrictions only one

Pharma, Entrepreneur type (only when searching in Pharma, Entrepreneur name or number): license holder manufacturer/final release distributor

Substance type (only when searching in substance name or substance number): Medicinally active ingredients ("active ingredients")

delete posting start search

4. Selanjutnya akan muncul hasil pencarian seperti pada gambar dibawah ini

Search wording: drug name="Myambutol"?

marketable medicines

Number of hits in the Drugs module: 3

abbreviation	surname	Info	hit
BNAMPU	AMCo Medicinal Products Public View	to	3
		from	0

Documents Found: 3

Title 1-3 of 3 of all selected databases

No.	drug name	dosage form	Marketing Authorization Holder	entry number	Approval no./reg. no.	version
1.	Myambutol 400 mg	film-coated tablet	Wohlpharma GmbH	2163184	61186.01.00	12.0.0
2.	Myambutol 400 mg	film-coated tablet	ACO Müller AG&Co. Pharma	2163308	61705.01.00	7.0.0
3.	Myambutol 400 mg	film-coated tablet	Entec Pharmaceuticals GmbH	0700286	6193748.01.01	22.0.1%

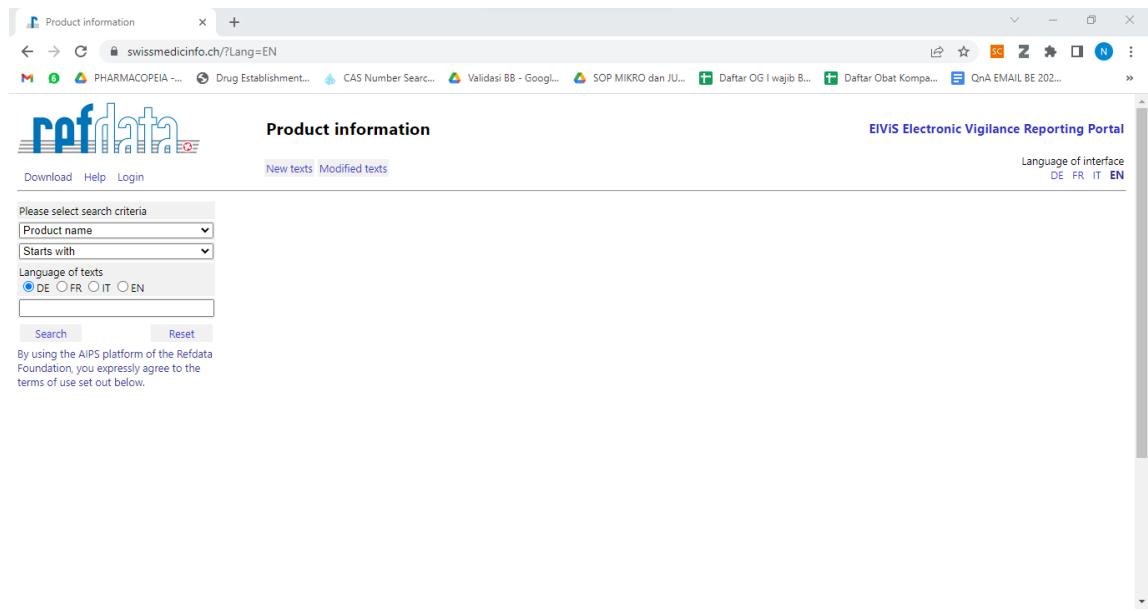
Registration holders and parallel distributors of central approvals (possibly different) are also column under approval holder.

select all documents on this page
 select all documents

start

6) Penelusuran obat komparator yang terdaftar di Swiss

1. Ketik alamat *website* sebagai berikut <https://tinyurl.com/search-CHE> pada *browser* anda. Setelah terkoneksi, akan muncul tampilan *website* pencarian produk milik *regulatory authority* negara Swiss.



Product information

swissmedicinfo.ch/?Lang=EN

Product information

EIViS Electronic Vigilance Reporting Portal

Please select search criteria

Product name

Starts with

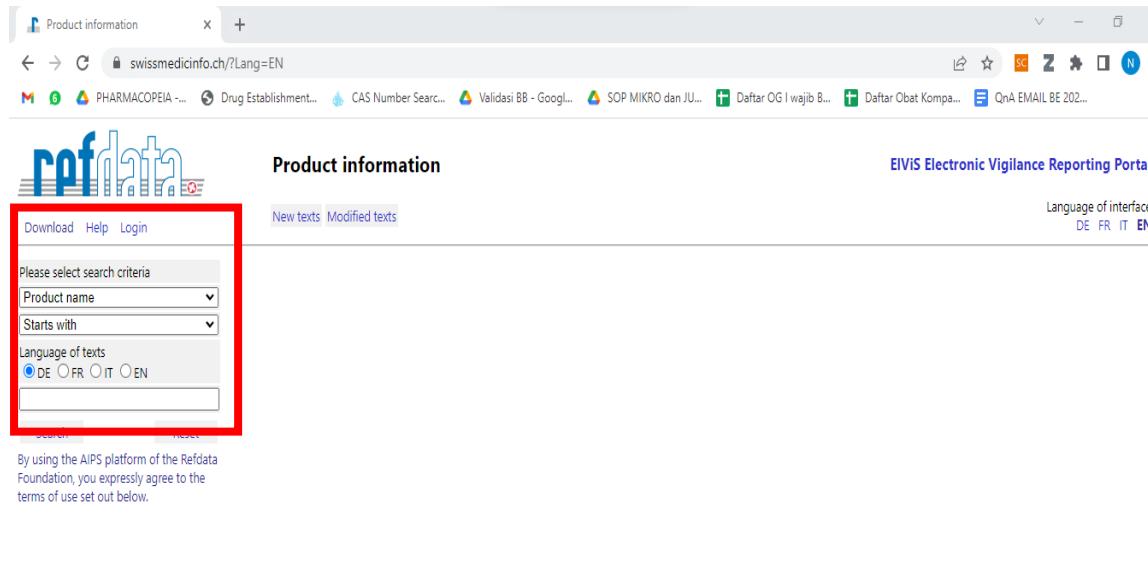
Language of texts

DE FR IT EN

Search Reset

By using the AIPS platform of the Refdata Foundation, you expressly agree to the terms of use set out below.

2. Pada bagian yang ditandai warna merah, ketikkan nama produk yang akan dicari. Kemudian klik **Search**.



Product information

swissmedicinfo.ch/?Lang=EN

Product information

EIViS Electronic Vigilance Reporting Portal

Please select search criteria

Product name

Starts with

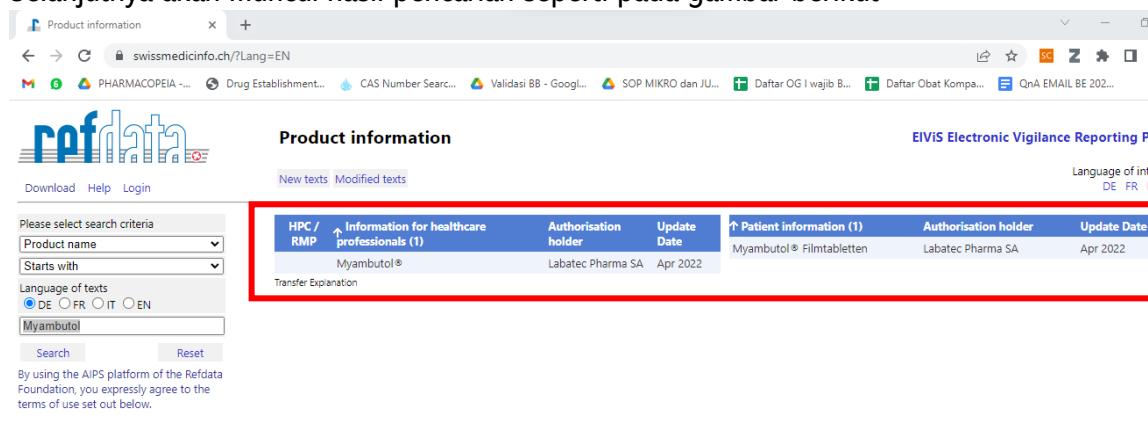
Language of texts

DE FR IT EN

Search Reset

By using the AIPS platform of the Refdata Foundation, you expressly agree to the terms of use set out below.

3. Selanjutnya akan muncul hasil pencarian seperti pada gambar berikut



Product information

swissmedicinfo.ch/?Lang=EN

Product information

EIViS Electronic Vigilance Reporting Portal

Please select search criteria

Product name

Starts with

Language of texts

DE FR IT EN

Myambutol

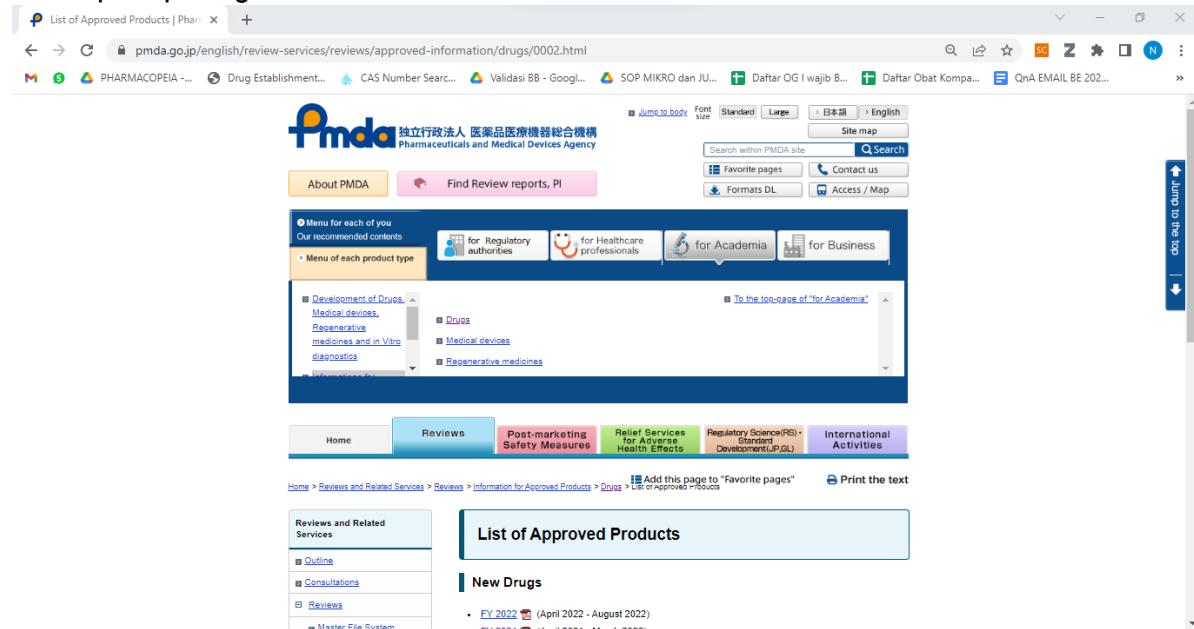
Search Reset

By using the AIPS platform of the Refdata Foundation, you expressly agree to the terms of use set out below.

HPC / RMP	Information for healthcare professionals (1)	Authorisation holder	Update Date	Patient information (1)	Authorisation holder	Update Date
	Myambutol® Transfer Explanation	Labatec Pharma SA	Apr 2022	Myambutol® Filmtabletten	Labatec Pharma SA	Apr 2022

7) Penelusuran obat komparator yang terdaftar di Jepang

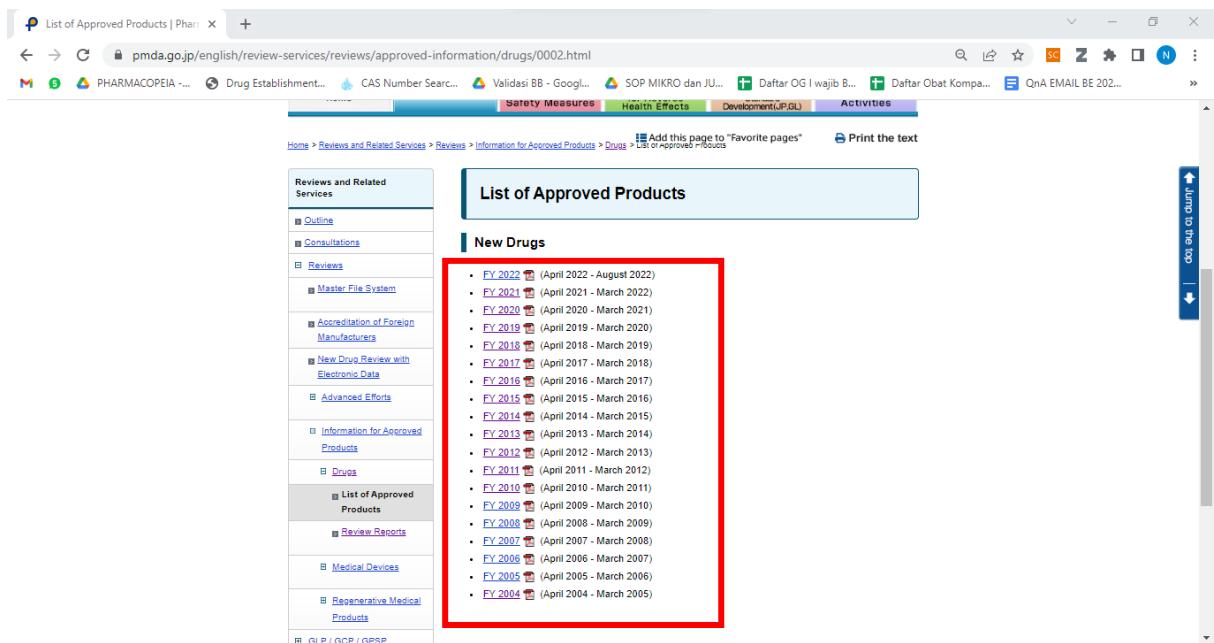
1. Ketik alamat *website* sebagai berikut <https://tinyurl.com/search-PMDA> pada *browser* anda. Setelah terkoneksi, akan muncul tampilan *website* pencarian produk milik PMDA seperti pada gambar di bawah.



The screenshot shows the PMDA website with the following details:

- Header:** PMDA logo, site map, search bar, and various navigation links.
- Left Sidebar:** 'Reviews and Related Services' menu with options like Outline, Consultations, Reviews, and Drugs.
- Content Area:** 'List of Approved Products' section for 'New Drugs'. It shows a list of drug approvals from FY 2004 to FY 2022.
- Footer:** Breadcrumbs, add to favorites, print text, and other site links.

2. Penelusuran obat komparator yang terdaftar di Jepang dapat dengan cara meng-klik file PDF pada bagian yang diberi tanda merah berikut ini.



The screenshot shows the PMDA website with the following details:

- Header:** PMDA logo, site map, search bar, and various navigation links.
- Left Sidebar:** 'Reviews and Related Services' menu with options like Outline, Consultations, Reviews, and Drugs.
- Content Area:** 'List of Approved Products' section for 'New Drugs'. It shows a list of drug approvals from FY 2004 to FY 2022.
- Footer:** Breadcrumbs, add to favorites, print text, and other site links.

8) Penelusuran obat komparator yang terdaftar di Singapura

1. Ketik alamat *website* sebagai berikut <https://tinyurl.com/search-HSA> pada *browser* anda. Setelah terkoneksi, akan muncul tampilan *website* pencarian produk milik HSA seperti pada gambar di bawah.

PZ4970 INFOSEARCH - REGISTER OF THERAPEUTIC PRODUCTS

This search enables you to get a listing of all registered Therapeutic Products in Singapore and their current approved Package Inserts (PIs)/Patient Information Leaflets (PILs).
Note: Not all PIs and PILs are currently available online

Search Product Names starting with:

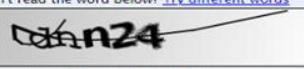
Click on a letter to list all Therapeutic Products Registrations where the product name starts with that letter.
0 1 2 3 4 5 6 7 8 9 A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

Search Therapeutic Products using search criteria below:

Registration No:	Containing <input checked="" type="checkbox"/>	<input type="text"/>	(eg.SIN99999P)
Product Name:	Containing <input checked="" type="checkbox"/>	<input type="text"/>	
Forensic Classification:	<input type="text"/>		
Approval Date:	<input type="text"/>	to	<input type="text"/>
Active Ingredient(s)	<input checked="" type="checkbox"/> AND / <input type="checkbox"/> OR <input checked="" type="checkbox"/> AND / <input type="checkbox"/> OR <input checked="" type="checkbox"/> AND / <input type="checkbox"/> OR <input checked="" type="checkbox"/> AND / <input type="checkbox"/> OR		

Security Check:

Can't read the word below? [Try different words](#)



Please enter the word you see above:

2. Pada bagian **Product Name**, ketikkan nama produk yang akan dicari. Misalnya produk yang akan dicari adalah 'LOSEC'. Kemudian ketikkan **security check** sesuai dengan yang tertera pada box lalu klik **Search**.

Search Product Names starting with:
 Click on a letter to list all Therapeutic Products Registrations where the product name starts with that letter.
0 1 2 3 4 5 6 7 8 9 A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

Search Therapeutic Products using search criteria below:

Registration No:	Containing <input checked="" type="checkbox"/>	<input type="text"/>	(eg.SIN99999P)
Product Name:	Containing <input checked="" type="checkbox"/>	<input type="text" value="LOSEC"/>	
Forensic Classification:	<input type="text"/>		
Approval Date:	<input type="text"/>	to	<input type="text"/>
Active Ingredient(s)	<input checked="" type="checkbox"/> AND / <input type="checkbox"/> OR <input checked="" type="checkbox"/> AND / <input type="checkbox"/> OR <input checked="" type="checkbox"/> AND / <input type="checkbox"/> OR <input checked="" type="checkbox"/> AND / <input type="checkbox"/> OR		

Security Check:
 Can't read the word below? [Try different words](#)

Please enter the word you see above:

Search

If "Exactly" is selected the search will return only records with the exact matching.
 If "Containing" is selected the search will return all results where the specified text appears somewhere in the selected field.
 For example: Name Containing 'ABC' will return 'ABC Trading' and 'Company ABC Pte Ltd'.

[Back to Infosearch](#)

Selanjutnya akan muncul hasil pencarian seperti pada gambar di bawah ini

PZ4971 INFOSEARCH - REGISTER OF THERAPEUTIC PRODUCTS

Therapeutic Products Listing

Search Criteria:

Brand Name: Containing LOSEC

Sort Result By: Product Name Ascending Descending

1 Records

S/No	Product Name	Registration No	Registrant
1	LOSEC MUPS TABLET 20 mg	SIN10700P	ZUELLIG PHARMA PTE. LTD.

1 Records

Page 1 Of 1 [First] | [Previous] | [Next] | [Last]

Page 1 Of 1 [First] | [Previous] | [Next] | [Last]

[Back to InfoSearch For Therapeutic Products](#)



Pada bagian *Registration No* dapat diklik untuk mendapatkan informasi mendetail terkait produk tersebut.

3. Pencarian juga dapat dilakukan dengan mengetikkan nama zat aktif pada bagian *Active Ingredient(s)*. Misalnya zat aktif yang akan dicari adalah 'OMEPRAZOLE' maka ketikkan 'OMEPRAZOLE' pada bagian kotak *Active Ingredient(s)* kemudian isi *security check* lalu klik *Search*.

PZ4970 INFOSEARCH - REGISTER OF THERAPEUTIC PRODUCTS

This search enables you to get a listing of all registered Therapeutic Products in Singapore and their current approved Package Inserts (PIs)/Patient Information Leaflets (PILs).
Note: Not all PIs and PILs are currently available online

Search Product Names starting with:
Click on a letter to list all Therapeutic Products Registrations where the product name starts with that letter.
0 1 2 3 4 5 6 7 8 9 A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

Search Therapeutic Products using search criteria below:

Registration No:	Containing	<input type="text"/>	(eg.SIN99999P)
Product Name:	Containing	<input type="text"/>	
Forensic Classification:	<input type="text"/>	<input type="button" value="to"/>	<input type="text"/>
Approval Date:	<input type="text"/>	<input type="button" value="to"/>	<input type="text"/>
Active Ingredient(s) Is Exactly <input checked="" type="radio"/> OMEPRAZOLE Containing <input type="radio"/> Containing <input type="radio"/> Containing <input type="radio"/>			
<input type="radio"/> AND / <input checked="" type="radio"/> OR <input checked="" type="radio"/> AND / <input type="radio"/> OR <input checked="" type="radio"/> AND / <input type="radio"/> OR			
Security Check: Can't read the word below? Try different words  Please enter the word you see above: <input type="text" value="5gx37"/>			
<input type="button" value="Search"/>			

Selanjutnya akan muncul hasil pencarian seperti pada gambar di bawah ini

PZ4971 INFOSEARCH - REGISTER OF THERAPEUTIC PRODUCTS

Therapeutic Products Listing		Search Criteria:	
Ingredient:	Containing:	OMEPRAZOLE	
Sort Result By:	Product Name	Ascending	Descending
36 Records			
S/N	Product Name	Registration No.	Registrant
1	EMANERA GASTRO-RESISTANT CAPSULES 20 MG	SINT15234P	SINGAPORE PHARMACEUTICAL PRIVATE LIMITED
2	EMANERA GASTRO-RESISTANT CAPSULES 40 MG	SINT15235P	SINGAPORE PHARMACEUTICAL PRIVATE LIMITED
3	EMAZOLE POWDER FOR SOLUTION FOR INJECTION/INFUSION 40 MG / VIAL	SINT15500P	PFIZER PRIVATE LIMITED
4	EPIVETIER POWDER FOR SOLUTION FOR INJECTION OR INFUSION 40MG PER VIAL	SINT15395P	GOLDPLUS UNIVERSAL PTE LTD
5	ESMOZIN POWDER FOR SOLUTION FOR INJECTION AND INFUSION 40 MG / VIAL	SINT16074P	PHARMAKOH PTE. LTD.
6	ES02 TABLETS 20MC	SINT14632P	RANBAXY (MALAYSIA) SDN. BHD.
7	ES02 TABLETS 40MC	SINT14622P	RANBAXY (MALAYSIA) SDN. BHD.
8	JUBIUM-20 GASTRO RESISTANT TABLETS 20MG	SINT15355P	GOLDPLUS UNIVERSAL PTE LTD
9	JUBIUM-40 GASTRO RESISTANT TABLETS 40MG	SINT15354P	GOLDPLUS UNIVERSAL PTE LTD
10	LOSEC MUPS TABLET 20 mg	SINT10760P	ZUELLIC PHARMA PTE. LTD.

36 Records

Page 1 Of 4 [First] | [Previous] | [Next] | [Last]

[Back to InfoSearch For Therapeutic Products](#)



PEOPLE - LEADERS

9) Penelusuran obat komparator yang terdaftar di Filipina

1. Ketik alamat *website* sebagai berikut <https://tinyurl.com/search-FDAPHL> pada *browser* anda. Setelah terkoneksi, akan muncul tampilan *website* pencarian produk milik FDA Phillipines seperti pada gambar di bawah:

First	Previous	1-10	11	12	13	14	15	16	17	18	19	20	21-30	Next	Last	Records 341 to 360 of 28705	
20	2																
Registration Number	Generic Name	Brand Name	Dosage Strength	Dosage Form	Manufacturer	Country of Origin	Application Type										
View BR-338	Inactivated Hepatitis A Vaccine	Havrix 1440	1440 ELISA Units/mL	Suspension for Injection (I.M.)	GlaxoSmithKline Biologicals S.A.	Belgium	-	1									
View BR-341	Live, Attenuated Varicella	Varilrix	After reconstitution, each dose (0.5mL) contains: Live, Attenuated Varicella Vaccine (OKA Strain) NLT 2,000 PFU	Lyophilized Powder for Injection (S.C.) Monodosage (see formulation on reverse side)	GlaxoSmithKline Biologicals S.A.	Belgium	-	1									
View BR-349	Measles Vaccine (Live Attenuated)	M-Vac	None	Lyophilized Powder for Injection (SC)	Serum Institute of India Ltd.	India	-	2									

2. Pada kotak ketikkan nama produk atau zat aktif yang akan dicari, lalu klik search.

FDA Food and Drug Administration Philippines

Contact Us | Correction/Addition Request

All Drug Products

Search Search

Registration Number	Generic Name	Brand Name	Dosage Strength	Dosage Form	Manufacturer	Country of Origin	Application Type	Issuance Date
BR-041-03	Enoxaparin Sodium	Enoxicare-40	4000 IU Anti-Factor Xa (equivalent to 40 mg) / 0.4 mL	Solution For Injection (SC)	Brawn Laboratories Ltd.	India	-	25 Apr 2014
BR-1000	Japanese Encephalitis Virus (Live, Attenuated, Recombinant)	IMOJEV	4.0-5.8 log 10 PFU** per dose (0.5mL)	Suspension for Injection (S.C.)	Government Pharmaceutical Organization-Mérieux Biological Products Co., Ltd.	Thailand	-	16 Dec 2014
BR-1001	Phospholipid Fraction from Bovine Lung	Alveofact	45 mg/mL (54 mg/1.2 mL)	Lyophilized powder for Suspension for Intratracheal	BAG Health Care GmbH	Germany	-	11 Mar 2014

Selanjutnya akan muncul hasil pencarian seperti pada gambar dibawah ini

FDA Food and Drug Administration Philippines

Contact Us | Correction/Addition Request

All Drug Products

Search Search

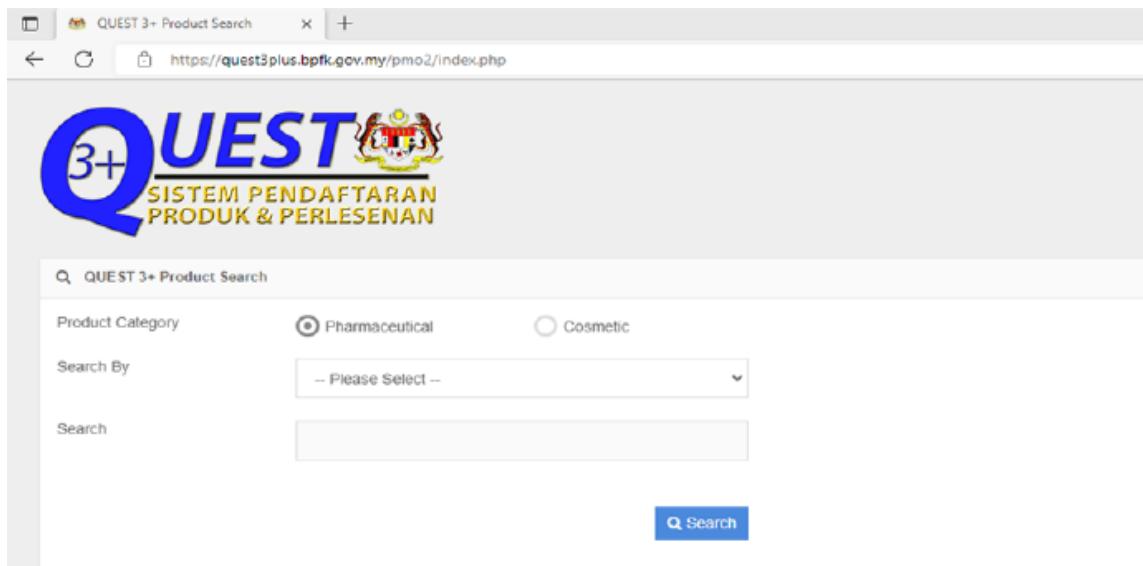
Registration Number	Generic Name	Brand Name	Dosage Strength	Dosage Form	Manufacturer	Country of Origin	Application Type	Issuance Date
DR-XY18046	Omeprazole	Losec	10 mg	Capsule	AstraZeneca AB	Sweden	-	04 April 2014
DR-XY18227	Omeprazole	Losec	20mg	Capsule	AstraZeneca AB	Sweden	-	19 October 2021

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Pada bagian 'view' dapat diklik untuk mendapatkan informasi yang lebih lengkap mengenai produk yang dicari.

10) Penelusuran obat komparator yang terdaftar di Malaysia

1. Ketik alamat *website* sebagai berikut <https://tinyurl.com/search-NPRA> pada *browser* Anda. Setelah terkoneksi, akan muncul tampilan *website* pencarian produk milik NPRA seperti pada gambar di bawah



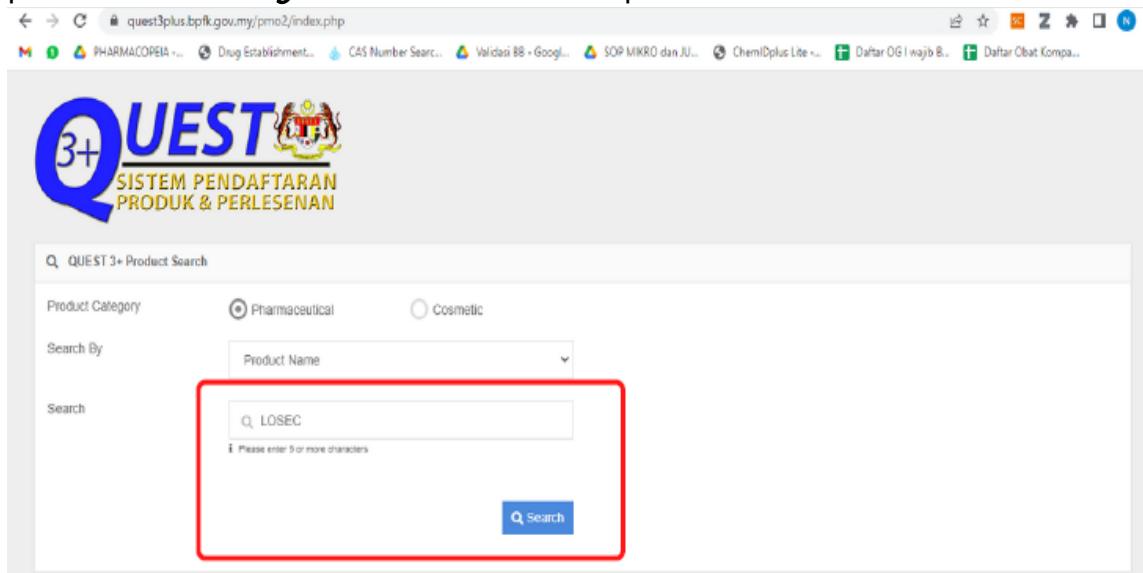
QUEST 3+ Product Search

Product Category Pharmaceutical Cosmetic

Search By

Search

2. Pada bagian **Search By**, pilih **Product Name** untuk melakukan pencarian berdasarkan nama produk atau **Active Ingredients** untuk melakukan pencarian berdasarkan nama zat aktif.



quest3plus.bpfk.gov.my/pmo2/index.php

PHARMACOPEIA ... Drug Establishment... C45 Number Search... Valida... SOP MIKRO dan JU... ChemiDplus Lite... Daftar OGI wajib ... Daftar Obat Kompa...

QUEST

SISTEM PENDAFTARAN PRODUK & PERLESENAN

QUEST 3+ Product Search

Product Category Pharmaceutical Cosmetic

Search By

Search
Please enter 5 or more characters

Selanjutnya akan muncul hasil pencarian seperti pada gambar di bawah.

#	Registration No / Notification No	Product Name	Holder
1	MAL 19992064AZ	LOSEC MUPS 10MG TABLET	ZUELLIG PHARMA SDN BHD
2	MAL 19992065AZ	LOSEC MUPS 20MG TABLET	ZUELLIG PHARMA SDN BHD

Pada bagian *Registration No / Notification No* dapat diklik untuk mendapatkan informasi mendetail terkait produk yang sedang dicari

PENGADAAN OBAT KOMPARATOR

Pengadaan obat komparator di luar negeri dapat dilakukan dengan bantuan agen/ pihak ketiga untuk membantu pencarian produk tersebut dan mendatangkannya ke Indonesia sesuai dengan mekanisme dan ketentuan yang berlaku (jalur pengadaan SAS).

Daftar agen/ pihak ketiga yang dapat dihubungi dapat dilihat pada tabel di bawah:

Nama Agen	Nama Agen
Pharmabiz, Korea	Alliance Pharma PTE LTD.
BM CLINICAL BV, Netherlands	Cubix Pharmaceuticals Ltd., United Kingdom
PCI Pharma Services, United Kingdom	Healol Pharmaceutical Sdn. Bhd. Malaysia
LINK HEALTHCARE SINGAPORE PTE. LTD.	WEP Clinical, United Kingdom
ESSENTIALS PHARMACY, Singapore	FARMACIE PETRONE S.R.L., Italia
ACETO GmbH, Jerman	Clinigen Inc., USA
Durbin PLC, United Kingdom	Anspec Pty. Ltd., Australia