Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

06 February 2017

DEPARTMENT MEMORANDUM
No. 2017 - 0068

TO : **ALL GOVERNMENT HOSPITAL CHIEF PHARMACISTS, NEUROLOGISTS, HOSPITAL DIRECTORS AND MEDICAL CENTER CHIEFS REQUESTED TO BE INCLUDED IN THE STROKE MEDICINES ACCESS PROGRAM (StrokeMAP)**

SUBJECT : **Additional FDA Approved Indication for Alteplase Products under the Stroke Medicines Access Program (StrokeMAP)**

The Pharmaceutical Division (PD) issued Department Memorandum No. 2016-0443 dated 12 December 2016 regarding the guidelines for hospitals in executing Deed of Donation and stock transfer of alteplase to other hospitals which may be needing this life-saving drug.

To further improve the utilization of Alteplase 50 mg vials particularly those nearing expiry, all stocks which have a remaining shelf life of six (6) months or less will now be allowed to be used by patients with **acute thrombotic coronary artery occlusion** and **pulmonary embolism** which are approved indications for use by the Philippine FDA. Please be reminded that Alteplase should only be given for the aforementioned indications and no other indications will be considered for this medicine (please see the attached certification of FDA).

For strict compliance.

By Authority of the Secretary of Health:

MARIO C. VILLAVERDE, MD, MPH, MPM, CESO I
Undersecretary of Health
Office for Health Regulation

REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF HEALTH
BUREAU OF FOOD AND DRUGS
ALABANG, MUNTINLUPA
Metro Manila

№ 013539

P.S.D. Form No. 1
Registration Status :
BFAD Registration No. : DR-XY7094
Classification : Rx/renewal

CERTIFICATE OF PRODUCT REGISTRATION

Pursuant to the provisions of Republic Act No. 3720 as amended, known as the Foods, Drugs and Devices and Cosmetics Act, and consistent with R.A. 6675, known as the Generic Act of 1988, the product more particularly described hereunder has been found to conform with requirements and standards for registration of pharmaceutical products per A.O. No. 67 s. 1989.

Name of Product : Generic : RECOMBINANT HUMAN TISSUE TYPE PLASMINOGEN ACTIVATOR

Brand (if any) : ACTILYSE 50 mg INFUSION

Manufacturer / Trader : Boehringer Ingelheim Int'l. GmbH
Germany

Imported by : Boehringer Ingelheim (Phils.), Inc.
Makati, Metro Manila

Approved Indication (s) : For fibrinolytic therapy in acute thrombotic coronary artery occlusion and pulmonary embolism.

Claimed Stability : 36 months

This registration shall be valid for 5 year(s) and shall expire on June 28, 1999, subject to the following conditions:

No change in the formulation, labelling and commercial presentation of this product shall be made during the effectivity of this registration without the approval of this Office.

This registration is subject to suspension, cancellation or recall should violation of any provision of R.A. 3720, as amended, and/or regulations issued thereunder involving the product be committed.

Witness My Hand and Seal of this Office, this 28th day of June, 1994.

R.L. P3,800 (Vial)
1703229
12-7-93
JC/emily
89-02-4037

QUINTIN L. KINTANAR, M.D., Ph. D.
Director - CESO I

The validity of this CPR is extended for another 6 months from JUNE 28, 2001 unless earlier cancelled or revoked.
Valid until DEC 28, 2001

9.17.01

RENEWAL
RSN 99A-295

Date Received: 6/15/99 CR # 72014SH

validity of this CPR is extended for one year from June 28, 1999 unless earlier cancelled or revoked.
Valid until June 28, 2000

The validity of this CPR is further extended until June 28, 2001

CBD Evaluator

OIC, Product Services Division

REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF HEALTH
BUREAU OF FOOD AND DRUGS
D.O.H. Compound
Alabang, Muntinlupa, M.M.

August 18, 1993

Ms. Susan B. Florentino
Boehringer Ingelheim
Makati, Metro Manila

Dear Ms. Florentino:

Re: Recombinant Human Tissue Plasminogen Activator (Actilyze) 50 mg per 5 ml

We wish to inform you of the approval of the additional indication of Actilyze: Pulmonary Embolism.

Thank you.

Very truly yours,

QUINTIN L. KINTANAR, M.D., Ph.D., CESO I
Director

QLK/FPG/emelyn

/actilyze

REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF HEALTH
BUREAU OF FOOD AND DRUGS
Filinvest Corporate City
Alabang, Muntinlupa City

MALAYA AT MALUSOG NA PAMAYANAN

June 9, 1999

MS. SUSAN B. TOLENTINO
Boehringer Ingelheim
Makati City

Re: Recombinant Tissue Plasminogen (Actilyze)

Dear Ms. Florentino:

We wish to inform you of the approval of the additional indication for Actilyze: *Treatment of Ischemic Stroke within 3 hours of symptom onset".* The updated package insert is likewise approved.

Thank you.

Very truly yours,

WILLIAM D. TORRES, Ph. D.
Director

Ref. # 98-1439
FPG/jhet
/b-ingelheim~actilyze