इंडियन इम्यूनोलाजिकल्स लिमिटेड
INDIAN IMMUNOLOGICALS LIMITED
ह्युमन बायोलाजिकल्स इंस्टिट्यूट
HUMAN BIOLOGICALS INSTITUTE
(A division of Indian Immunologicals Limited)

Date: 27.12.2018

TO WHOMSOEVER IT MAY CONCERN

The Following are the countries where the Abhayrab (Rabies vaccine BP) is registered

S. No.	Name of the Country	Registration Number
1.	Philippines	BR-629
2.	Kenya	13850
3.	Thailand	IC 22/50
4.	Pakistan	045701
5.	Turkey	6502
6.	Vietnam	QLVX-0805-14
7.	Zambia	088/001
8.	Botswana	BOT1202213
9.	Gabon	N°6952/14
10.	Congo	VC-PSM/MI-Vac/4.01.3 B/N° 3 AHS2
11.	Ivory coast	2451
12.	Uganda	9349/19/16
13.	Bhutan	BHU-DRA/B02899
14.	Tajikistan	8054
15.	Zimbabwe	2017/18.2/5468

The Copy of Registration certificates have been enclosed

For Human Biologicals Institute
(A Division of Indian Immunologicals Ltd.)

27.12.2018
(Anjaiah Enugula)
Manager – Regulatory Affairs

संयंत्र : कोलीपन्नाई, पुदुमंद पी.ओ., उदगमंडलम - 643 007, टी.एन्., भारत • दूरभाष : +91-423-2443186, 2441928 • फैक्स : +91-423-2442048
Plant : Kozhipannai, Pudumund P.O., Udhagamandalam - 643 007, T.N., India • Phones : +91-423-2443186, 2441928 • Fax : +91-423-2442048
पंजीकृत कार्यालय : रोड नंबर 44, जूबिलीहिल्स, हैदराबाद - 500 033 टी.जी., भारत • दूरभाष : +91-40-23544585, 23544593 • फैक्स : +91-40-23544007
Regd. Office : Road No. 44, Jubilee Hills, Hyderabad - 500 033, T.G., India • Phones : +91-40-23544585, 23544593 • Fax : +91-40-23544007
CIN: U72200TG1999PLC032666 E-mail: info@indimmune.com Website: www.indimmune.com

- retirer immédiatement du marché congolais la totalité de ABHAYRAB, vaccin antirabique dont l'AMM est suspendue ou arrivée à expiration ;
- assumer l'entière responsabilité de tout incident pouvant subvenir au niveau de la protection du brevet de ABHAYRAB, vaccin antirabique

En cas d'inobservation de ces engagements, l'autorisation de mise sur le marché, après mise à demeure, est de facto suspendue ou retirée.

Article 5 :
Le prix grossiste hors-taxe négocié et accordé est de 4 920 F.CFA

Article 6 :
Dans l'état actuel du dossier, la durée de conservation est de : 36 mois

Article 7 :
Toute information sur le produit, quel qu'en soit le support et destinée aux personnels de santé ou au public, doivent être conformes aux mentions contenues dans le résumé caractéristique du produit (RCP) et sa diffusion est assujettie à une autorisation préalable de l'autorité nationale de réglementation pharmaceutique.

Article 8 :
La présente autorisation, à la demande de son titulaire, ne sera renouvelée qu'avant la date butoir du 28 février 2019. Elle, non renouvelée, devient caduque, sauf cas de force majeur empêchant le fonctionnement régulier des services du ministère de la santé, le 1er avril 2019.

Article 9 :
La présente décision prend effet à compter de sa date de signature./-

Fait à Brazzaville, le 01.04.2015
Pour le ministre de la santé et par autorisation,
le directeur de la pharmacie et du médicament

MINISTERE DE LA SANTE ET DE LA POPULATION * République du Congo * DIRECTION DES PHARMACIES ET DU MEDICAMENT * Le Directeur

Dr Aimé Antoine EKAKA
Pharmacien

MINISTERE DE LA SANTE
ET DE LA LUTTE CONTRE LE SIDA
-=-=-=-=-
DIRECTION GENERALE DE LA SANTE
-=-=-=-=-
DIRECTION DE LA PHARMACIE,
DU MEDICAMENT & DES LABORATOIRES

N°2133 /MSLS/DGS/DPM-/DAR/KBAAG

REPUBLIQUE DE COTE D'IVOIRE
Union – Discipline – Travail
-=-=-=-

Abidjan, le 01 SEP 2015

Objet : **Inspection d'unité de production de médicaments.**

Monsieur le Directeur Général,

Suite à l'inspection effectuée le 29 juin 2015, en **INDE** par une délégation d'inspecteurs du Ministère chargé de la Santé, dans l'unité de production de médicaments ci-après désignée :

- **HUMAN BIOLOGICAL INSTITUTE.**

J'ai l'honneur de vous transmettre le rapport de visite de ladite unité.

Le certificat de Bonnes Pratiques de Fabrication (BPF) est joint en annexe.

Veuillez agréer, **Monsieur le Directeur Général,** l'expression de ma considération distinguée.

Le Directeur

Docteur DUNCAN A. Rachel

Monsieur le **Directeur Général**
Laboratoires **HUMAN BIOLOGICAL INSTITUTE.**
Kozhipannal, pudumund Post Dr. Basavalah nagar Udhagamandalam-643 007 Tamil nadu.
INDE

MINISTERE DE LA SANTE
ET DE LA LUTTE CONTRE LE SIDA
-=-=-=-=-
DIRECTION GENERALE DE LA SANTE
-=-=-=-=-
DIRECTION DE LA PHARMACIE,
DU MEDICAMENT & DES LABORATOIRES

N°2133 /MSLS/DGS/DPM_/DAR/KBAAG

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-=-=-=-=-

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Le Directeur

Docteur DUNCAN A. Rachel

Monsieur le Directeur Général
Laboratoires **HUMAN BIOLOGICAL INSTITUTE.**
Kozhiponnal, pudumund Post Dr. Basavaiah nagar Udhagamandalam-643 007 Tamil nadu.
INDE

NATIONAL DRUG AUTHORITY

Safe Drugs Save Lives

16th June 2016

Ref: 1367/DR/NDA-06/2016

Indian Immunologicals Limited
INDIA

REGISTRATION OF PHARMACEUTICAL PRODUCT

We are pleased to inform you that, the drug below for which you had applied for registration in Uganda has been approved.

FILE NO.	MANUFACTURER	DRUG NAME	STRENGTH	GENERIC NAME	DOSAGE FORM	PACK SIZE	LICENCE HOLDER	COUNTRY	LTR	CLASS	REG NO
L166	HUMAN BIOLOGICALS INSTITUTE (A DIVISION OF INDIAN IMMUNOLOGICALS LTD) KOZHIPANNAI PUDUMUND P O DR. BASAVAIAH NAGAR UDHAGAMANDALAM PIN 643007 TAMIL NADU	AIBHAYRAB	≥2 5 I U PER VIAL	RABIES VACCINE	FREEZE DRIED VACCINE	1*1 VIAL + 1*0 5ML DILUENT (0 9%W/V SODIUM CHLORIDE INJ. B P)	INDIAN IMMUNOLOGICALS LIMITED	INDIA	TATA UGANDA LIMITED	VACCINE	9349/19/16

Payment of the retention fee to maintain this product on the register is due on 1st July 2018.

Other products manufactured by your company, including products of the same name manufactured in a different place from that applied for, may not be imported into Uganda unless specially approved by the National Drug Authority.

Registration of a drug does not exempt the applicant and/or manufacturer or his agent from any other enforceable laws of Uganda or International laws or conventions more especially the patent rights, trade marks etc.

Continuous monitoring of your products in Uganda for compliance to quality standards shall be conducted. Any change in the information submitted to the National Drug Authority for the purpose of registration must be notified to the Authority within 30 days of the change, at a prescribed fee.

Your Local Technical Representative will be held responsible for all technical aspects of the product(s) marketed in Uganda, including but not exclusively:

- Obligation to notify changes in the product, including labelling, package insert information etc.
- Notification of any changes in the product information with regard to any newly identified adverse or side effects, drug interactions, warning etc.
- Responsibilities of any necessary product re-call on behalf of the manufacturer or applicant.
- Certifying proforma invoices from applicant/manufacturer.

Yours faithfully,
NATIONAL DRUG AUTHORITY

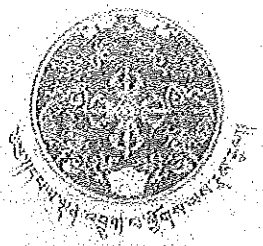
Donna Kusemererwa
EXECUTIVE DIRECTOR

Copy to: Tata Uganda limited

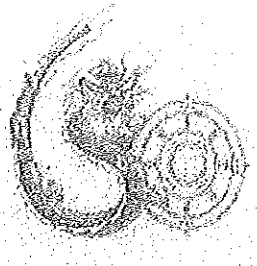
AD OFFICE
1 46-48 Lumumba Avenue
) Box 23095 Kampala, Uganda
(+256) 414 255685/347391/347392
+256 414 255758
line (+256) 414 344052, 776 110 008, 712 001 199
bsite www.nda.or.ug Email ndaug@nda.or.ug
acebook Uganda National Drug Authority
ter @UNDAuthority

OUR MISSION
To ensure access to quality, safe and Efficacious human and veterinary medicines And other healthcare products through the Regulation and control of their production, importation, distribution and use

REGIONAL OFFICES
Central Region, Nakawa - Tel +256 312 261 546,
Western Nile Region, Arua – Tel. +256 372 260 085/7,
South western Region, Mbarara – Tel. +256 485 421 088,
South Eastern Region, Jinja – Tel/Fax: +256 434122 176,
Eastern Region, Tororo –Tel +256 454 445 195,
Western Region, Hoima – Tel /Fax +256 465 440 688
Northern Region, Lira – Tel/Fax +256 473 420 652



Drug Regulatory Authority
Royal Government of Bhutan
P.O. BOX NO. 1556
THIMPHU, BHUTAN



Regulation No. 41

CERTIFICATE OF REGISTRATION OF MEDICINAL PRODUCT (S)

Registration No. BHU-DRA/B02899

The following medicinal product (s) is/are registered for sale/distribution in Bhutan under the provisions of the Medicines Act of the Kingdom of Bhutan 2003.

This registration is valid up to 31-May-19 (three years from the date of issue) unless it is earlier cancelled or suspended or revoked.

Name of the Product	Generic Name	Trade Name	
	Rabies vaccine, Human IP	Abhayrab	
Strength with Composition	Composition: Purified lyophilized Rabies antigen derived from Rabies Virus(L.Pasteur 2061/Vero Strain propagated in Vero cells) Inactivated. Ptency: ≥ 2.5 I.U per vial. Stabilizers: Maltose and Human Albumin..q.s, Preservative: Thiomersal 0.015% w/v.	Dosage Form	*Injectables*
		Pack size	*20 vials of vaccine*
		Type of packaging	*Vial*
Therapeutic Category	Vaccines		

Market Authorization Holder: Karma Pharmaceutical & Medical Supplies,Thimphu, Bhutan

Manufacturer: Human Biological institute. [A division of Indian Immunologicals Ltd), Tamil Nadu-IND

Marketed by: N/A

Conditions:

1. The Market Authorization shall abide by the duties and principles as specified under the Rules and Regulation.
2. The Market Authorization Holder shall be responsible for timely removal in case of confirmed defective medicinal products from the market

Date: 31-May-16

Drug Controller

Sonam Dorji
Drug Controller
Drug Regulatory Authority

ҶУМҲУРИИ ТОҶИКИСТОН
ХАДАМОТИ НАЗОРАТИ ДАВЛАТИИ
ФАЪОЛИЯТИ ФАРМАСЕВТӢ

734026, Тоҷикистон, ш. Душанбе,
к. А. Навоӣ, 5/5
тел.: (992 37) 235-77-15; факс: (992 37) 235-19-45

РЕСПУБЛИКА ТАДЖИКИСТАН
СЛУЖБА ГОСУДАРСТВЕННОГО НАДЗОРА ЗА
ФАРМАЦЕВТИЧЕСКОЙ ДЕЯТЕЛЬНОСТЬЮ

734026, Таджикистан, г. Душанбе,
ул. А. Навои, 5/5
тел.: (992 37) 235-77-15; факс: (992 37) 235-19-45

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ

Серия ЛС № 008054

Настоящее удостоверение выдано Evolet Healthcare Pvt. Ltd.

Индия, производитель: Human Biologicals Institute, Индия

в том, что в соответствии с Законом Республики Таджикистан «О лекарственных средствах и фармацевтической деятельности». лекарственное средство под названием

Абхайраб® вакцина антирабическая человеческая

в виде формы порошок для приготовления раствора для инъекций

по 0,5 мл (1 доза) во флаконах в комплекте с растворителем натрия хлорид 0,9% по 0,5 мл в ампулах и шприц одноразовый 2 мл с иглой №1

зарегистрировано в Республике Таджикистан.

ДАННОЕ УДОСТОВЕРЕНИЕ ДЕЙСТВИТЕЛЬНО В ТЕЧЕНИЕ 5 ЛЕТ
И НЕ ЯВЛЯЕТСЯ ОБЯЗАТЕЛЬСТВОМ В ЗАКУПКЕ ДАННОГО ИЗДЕЛИЯ

Дата регистрации « 11 » *мая* 2017 г.

Руководитель С.Б. Бекмуродзода

ҶУМҲУРИИ ТОҶИКИСТОН
ХАДАМОТИ НАЗОРАТИ ДАВЛАТИИ
ФАЪОЛИЯТИ ФАРМАСЕВТӢ

734026, Тоҷикистон, ш. Душанбе,
к. А. Навоӣ, 5/5
тел.: (992 37) 235-77-15; факс: (992 37) 235-19-45

РЕСПУБЛИКА ТАДЖИКИСТАН
СЛУЖБА ГОСУДАРСТВЕННОГО НАДЗОРА ЗА
ФАРМАЦЕВТИЧЕСКОЙ ДЕЯТЕЛЬНОСТЬЮ

734026, Таджикистан, г. Душанбе,
ул. А. Навои, 5/5
тел.: (992 37) 235-77-15; факс: (992 37) 235-19-45

ШАҲОДАТНОМАИ БАҚАЙДГИРӢ
РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ

Силсилаи ЛС № 008054

Шаҳодатномаи мазкур дода шуд ба Evolet Healthcare Pvt. Ltd.

Ҳиндустон, истеҳсолкунанда: Human Biologicals Institute, Ҳиндустон

дар хусуси он ки мутобиқи қонуни Ҷумҳурии Тоҷикистон «Дар бораи маводи дорувориӣ ва фаъолияти фармасевтӣ», маводи дорувориӣ бо номи

Абхайраб® вакцина антирабическая человеческая

дар шакли хока барои тайёр намудани маҳлул барои инъексия

0,5 мл (1 воя) дар шишадору дар якҷояӣ бо ҳалкунанда натрия

хлорид 0,9% 0,5 мл дар ампула ва сузандоруи 2 мл №1

дар Ҷумҳурии Тоҷикистон ба қайд гирифта шуд.

ШАҲОДАТНОМАИ МАЗКУР ДАР МУДДАТИ 5 СОЛ АМАЛ МЕКУНАД
ВА БАРОИ ХАРИДИ ДОРУВОРИИ МАЗКУР ЎҲДАДОР НАМЕКУНАД

Санаи бақайдгирӣ « 11 » *май* 2017 сол

Сардор С.Б. Бекмуродзода

07118

Medicines Control Authority of Zimbabwe

Medicines and Allied Substances Control Act (Chapter 15:03)

REGISTRATION CERTIFICATE

CONFIDENTIAL Number: 5468

IT is hereby certified that a medicine has been registered as follows:

1. Approved name of medicine: PURIFIED VERO CELL RABIES VACCINE
2. Trade mark of medicine: ABHAYRAB
3. The form in which the medicine is presented and the colour thereof: CREAMY WHITE COLOR FREEZE DRIED VACCINE, AFTER RECONSTITUTION VACCINE APPEARS AS A CLEAR SOLUTION AND USED AS AN INJECTION
4. Approved name of the active ingredient(s) and strength: PURIFIED VERO CELL RABIES VACCINE 2.5IU/0.55ML
5. Registration number of the medicine: 2017/18.2/5468
6. Shelf life of medicine in months: 36 MONTHS, WHEN STORED AT TEMPERATURES BETWEEN 2 – 8'C IN:
   I. TUBULAR CLEAR USP TYPE-I GLASS VIALS, 2ML WITH GREY BUTYL RUBBER BUNGS AND 13MM ALUMINIUM FLIP OFF SEALS
   II. USP TYPE-I GLASS FLINT AMPOULES WITH BLUE RING, 0,5ML
7. Category for distribution of medicine: PRESCRIPTION PREPARATIONS (P.P.)
8. Name and address of manufacturer(s): HUMAN BIOLOGICALS INSTITUTE, (A DIVISION OF INDIAN IMMUNOLOGICALS), KOZHIPANNAI, PUDUMUND POST, UDHAGAMANDALAM-643 007, TAMIL NADU, INDIA
9. Name and address of principal: HUMAN BIOLOGICAL INSTITUTE, INDIAN IMMUNOLOGICALS LIMITED, ROAD NO. 44 JUBILEE HILLS, HYDERABAD-500 033, INDIA
10. Name and address of applicant: HUMAN BIOLOGICAL INSTITUTE, INDIAN IMMUNOLOGICALS LIMITED, ROAD NO. 44 JUBILEE HILLS, HYDERABAD-500 033, INDIA
11. Address at which certificate will be kept: HUMAN BIOLOGICALS INSTITUTE, (A DIVISION OF INDIAN IMMUNOLOGICALS LIMITED), KOZHIPANNAI, PUDUMUND POST, UDHAGAMANDALAM (OOTY)-643 007, TAMIL NADU, INDIA
12. Date of original registration: 31ST OCTOBER 2017
13. The medicine will be: IMPORTED INTO Zimbabwe
14. Conditions of registration imposed by the Authority: SUBJECT TO COMPLIANCE WITH LABELLING REQUIREMENTS
15. Date of issue of certificate: 06 NOVEMBER 2017

Issued at Harare this 6TH DAY OF NOVEMBER 2017

.....
Director-General

This certificate must be returned to the Authority if cancelled, invalidated or if the registration of the medicine is withdrawn or when requested to do so by the Director-General. Failure to do so is an offence.

CERTIFICATE of REGISTRATION

FDA-20155AI.3HHC70...XXD1H

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA Food and Drug Administration PHILIPPINES

CERTIFICATE OF PRODUCT REGISTRATION

Pursuant to the provisions of Republic Act (R.A.) No. 3720 as amended, known as the Foods, Drugs, Devices and Cosmetics Act, and consistent with R.A. No. 6675, known as the Generics Act of 1988, and R.A. No. 9711, otherwise known as the Food and Drug Administration Act of 2009, the product described hereunder has been found to conform with the requirements and standards for marketing authorization of pharmaceutical products per existing regulations in force as of date hereof.

Registration Number	:	BR-629
Generic Name	:	Purified Vero Cell Rabies Vaccine
Brand Name	:	Abhayrab
Dosage Strength & Form	:	2.5 IU/0.5mL Freeze-Dried Powder for Injection (I.M./I.D.)
Pharmacologic Category	:	Vaccine
Classification	:	Prescription Drug (Rx)
Approved Shelf-life	:	36 months
Storage Condition	:	Store at 2°C to 8°C. Do not freeze.
Packaging	:	Clear, colorless glass vial + diluent ampoule (0.5mL) + 2 mL disposable syringe (in a plastic kit)
Manufacturer	:	Human Biologicals Institute (A Division of Indian Immunologicals Limited). Pudumund P.O., Udhagamandalam-643 007, Tamil Nadu, India
Importer	:	IP Biotech, Inc. 2nd Flr. Bonifacio Technology Center, 31st cor. 2nd Ave., Bonifacio Global City, Taguig City
Distributor	:	IP Biotech, Inc. 2nd Flr. Bonifacio Technology Center, 31st cor. 2nd Ave., Bonifacio Global City, Taguig City

The marketing authorization shall be valid until 21 February 2018 subject to the conditions listed on the reverse side. No change in the formulation, labelling and commercial presentation of this product shall be made at any time during the effectivity of this registration without prior written approval of this Office.

This marketing authorization is subject to suspension, cancellation or recall should any violation of R.A. No. 3720, R.A. No. 6675 and R.A. No. 9711 and/or regulations issued thereunder involving the product be committed.

Witness My Hand and Seal of this Office, this 20 April 2015.

BY AUTHORITY OF THE DIRECTOR-GENERAL

MELODY M. TAMUDIO, RPh, MGM-ESP
Officer-in-Charge
Center for Drug Regulation and Research

REG. STATUS	:	Renewal
OTHER RSN	:	CDRR20130219-00549
AMOUNT	:	Php10,100
OR NUMBER	:	6443702
DATE	:	19-Feb-2013
CODE	:	125-222-001
BAR CODE	:	
DOC TRACK	:	2014031118125 1

FDA-0142307

Registration Number : BR-629

SPECIAL CONDITION:

Provided that nothing in the registration of the product herein granted shall be interpreted or construed as an endorsement or representation by FDA, that Registrant has the right or privilege to the use of the name or brand so registered; Registrant hereby agrees and affirms to indemnify and/or hold FDA free and harmless against any and all third-party claims on infringement of patent, trademark or intellectual property right arising from the registration of the product.

	A	This is subject to batch notification.
X	B	This is subject to lot release certification.
	C	This is subject to compliance with the requirements under FDA Circular No. 2013-004 for Monitored Release (MR) drug products.
X	D	Submit commercial sample of the first batch of importation/manufacture/packing/repacking, for all pack sizes, including package insert or patient information leaflet as per approved label.
	E	For renewal registration, submit a satisfactory bioavailability/bioequivalence study report or biowaiver evidence (whichever is applicable) within ____ year(s) in accordance with FDA Circular 2013-014.
	F	Dangerous Drug - To be prescribed by PDEA S-2 licensed practitioner in a DOH (yellow) prescription form. It is a habit-forming drug.
	G	Dangerous Drug - To be prescribed by PDEA S-2 licensed practitioner in a personalized ordinary prescription. It is a habit-forming drug.
	H	For renewal registration, submit a Certificate of Good Manufacturing Practice (GMP) Compliance of Foreign Drug Manufacturer(s) within ___ year(s) in accordance with A. O. 2013-0022 and FDA Circular 2014-016.

REMARKS:

FDA 20180118172924

RENEWAL DTN : 20180129155705

OR No. : 0947523 Date Issued: 24 JAN 2018

The validity of this CPR is extended for one year from 21 FEB 2018 to 21 FEB 2019 unless earlier cancelled or revoked by this Office.

Pamela B. Festolerin
CDRR Evaluator

Atty. Katherine M. Austria-Lock
Officer-in-Charge, CDRR
for Director

1

REPUBLIC OF KENYA

MINISTRY OF MEDICAL SERVICES

PHARMACY AND POISONS BOARD

Telegram: "[illegible]", Nairobi
Telephone: [illegible]
Cellphone: [illegible]
Fax: [illegible]
E-mail: [illegible]

When replying please quote

PHARMACY AND POISONS BOARD HOUSE
LENANA ROAD
P.O. Box 27663-00506
NAIROBI

Ref. 909 | Date. 27/7/2011

Indian Immunologicals Ltd
C/o Surgipharm Ltd
P.O Box 46043 - 00100
NAIROBI.

Dear Sir,

RE: APPLICATION FOR RE-REGISTRATION OF DRUGS

The following product(s) has (have) been evaluated and approved for re-registration for the next five (5) years from the date of issue of this letter.

1. 13890 Abhayrab Vaccine 0.5ml ~~Vaccine~~
2.
3.
4.
5.
6.
7.
8.
9.
10.
11.
12.

DR. B. K. NJUE
FOR: REGISTRAR

แบบ ท.ย. ๑

ใบสำคัญการขึ้นทะเบียนตำรับยา
แผนปัจจุบัน
(นำหรือสั่งเข้ามาในราชอาณาจักร)

เลขทะเบียนที่ 1C 22/50

ใบสำคัญฉบับนี้แสดงว่า

ชื่อยา ABHAYRAB แอ็บเฮแรบ

ตามแบบ ท.ย. ๑ เลขรับที่ 1C 90083/47 เป็นยาชนิด ผงยาชีววัตถุ ปราศจากเชื้อสีขาว พร้อมน้ำยาทำละลายใส ไม่มีสี

ผลิตโดย HUMAN BIOLOGICALS INSTITUTE, A DIVISION OF INDIAN IMMUNOLOGICALS LIMITED

อยู่เลขที่ - ตรอก/ซอย - ถนน -

หมู่ที่ - ตำบล/แขวง PUDUMUND POST อำเภอ/เขต UDHAGAMANDALAM-643007

จังหวัด TAMIL NADU ประเทศ INDIA

ชื่อสถานที่นำหรือสั่งยาเข้ามาในราชอาณาจักร บริษัท นีโอฟาร์ม จำกัด

ใบอนุญาตเลขที่ 22/2534 อยู่เลขที่ 5/26-27 ตรอก/ซอย จุดทรัพย์

ถนน บรมราชชนนี หมู่ที่ - ตำบล/แขวง อรุณอมรินทร์

อำเภอ/เขต บางกอกน้อย จังหวัด กรุงเทพมหานคร โทรศัพท์ 02-9050951-4

ได้รับขึ้นทะเบียนไว้แล้ว

เมื่อวันที่ 30 เดือน มกราคม พ.ศ. 2550

ใบสำคัญการขึ้นทะเบียนตำรับยานี้มีอายุใช้ได้ตลอดเวลาที่ได้รับใบอนุญาตนำหรือสั่งยาเข้ามาในราชอาณาจักร

(นายวิไล บัณฑิตานุกูล)

[illegible]

[illegible] พนักงานเจ้าหน้าที่

No F. 3-7/2006-Reg-I(M-203)
Government of Pakistan
Ministry of Health

Islamabad, the 13.06.2007

M/s Cirin Pharmaceuticals (Pvt) Ltd.,
32-2-A, Industrial Estate,
Hattar, Distt. Haripur.

SUBJECT:- REGISTRATION OF DRUGS UNDER SECTION 7 OF THE DRUGS ACT, 1976 AND RULE 30 OF THE DRUGS (LICENSING, REGISTERING AND ADVERTISING) RULES, 1976.

The drug(s), as per details given below has/have been registered subject to the conditions appearing herein after: -

S.NO	REGN. NO.	NAME OF DRUG (S) & COMPOSITION.	PACKING (S)
1.	045701	Abhayrab Vaccine. Each Immunizing dose (0.5ml) contains:- Purified Vero Cell Rabies Vaccine Antigen (Inactivated) > 2.5 IU. Human Serum Albumin 12mg. Maltose 40 mg. Thiomersal 0.01%.	Per vial.

(Manufactured by M/s. Human Biological Institute, India).

CONDITIONS:

i). The Registration Number, Maximum Retail Price, Manufacturing/Expiry dates and other particulars shall be provided as per the Drugs (Labelling & Packing) Rules, 1986.

ii). Colour Scheme of the labels/labelling should not resemble with any of the drugs(s) which has/have already been registered.

iii) The name of the drug shall be changed in case it has resemblance/similarity with already registered drug.

iv). Every drug shall be imported in sufficient quantity so as to ensure its regular and adequate supply in the market.

v) The drug(s) must be marketed within six months of receipt of this communication.

vi) The import of any drug shall not, without the prior approval of the Registration Board, be discontinued for a period, which may result in its shortage.

vii) One copy of the complete method of testing of the finished drugs containing the full details of all minor and major steps and protocols along with specifications (lower and upper limits) shall be submitted to the following institutions within a period of one month: -

a. Chief, Drugs Control & Research Division, National Institute of Health Islamabad
b. Director, Central Drugs Laboratory, Building No 4, Block-B, S.M.C.H.S., Karachi.
c. Director, Drugs Testing Laboratory, 1-Bird Wood Road, Lahore
d. Director, Drugs Testing Laboratory, Government of Sindh, Karachi.
e. Director, Drugs Testing Laboratory, Government of N.W.F.P., Peshawar.

viii). One copy of the Master Formula (of all registered drugs), containing the name of active and inactive materials along with the quantities shall be furnished, to the concerned Assistant Drugs Controller, within a period of one month for which a receipt shall also be obtained.

FOR SECRETARY REGISTRATION BOARD

Copy for -

1. Deputy Director General (Pricing).
2. Assistant Drugs Controller (concerned).
3. Company's File.
4. Provincial Secretaries (Punjab, Sindh, NWFP, Baluchistan & AJK)
5. P.S. to Secretary (Health).

T.C. SAĞLIK BAKANLIĞI

TÜRKİYE İLAÇ VE TIBBİ CİHAZ KURUMU

RUHSATNAME

04.04.2018 tarih ve 2018/180 sayılı bu ruhsatname **ABHAYRAB 2.5 IU/0.5 ML IM/ID ENJEKSİYONLUK ÇÖZELTİ HAZIRLAMAK İÇİN LİYOFİLİZE TOZ VE ÇÖZÜCÜ** isimli beşeri tıbbi ürün için **YENİŞARK MÜMESSİL ECZA DEPOSU A.Ş.** firması adına tahsis edilmiştir.

Eki : Sertifika
Ruhsatname ID : 6502
İş bu ruhsatname eki sertifika ile geçerlidir

Dr. Hakkı GÜRSÖZ
Kurum Başkanı

T.C.
SAĞLIK BAKANLIĞI
Türkiye İlaç ve Tıbbi Cihaz Kurumu

Ruhsatname ID : 6502

Bu sertifika **04.04.2018** tarih ve **2018/180** sayılı Ruhsatname eki olarak **ABHAYRAB 2.5 IU/0.5 ML IM/ID ENJEKSİYONLUK ÇÖZELTİ HAZIRLAMAK İÇİN LİYOFİLİZE TOZ VE ÇÖZÜCÜ** isimli **İmmünolojik Ürün** için düzenlenmiştir.

REÇETELİ / REÇETESİZ	:	REÇETELİ
REÇETE TÜRÜ	:	BEYAZ REÇETE
RUHSAT SAHİBİ	:	YENİŞARK MÜMESSİL ECZA DEPOSU A.Ş.
ETKİN MADDE ADI	:	İNAKTİVE EDİLMİŞ & SAFLAŞTIRILMIŞ KUDUZ ANTİJEN KONSANTRESİ
ETKİN MADDE ÜRETİCİSİ	:	HUMAN BIOLOGICALS INSTITUTE (A DIVISION OF INDIAN IMMUNOLOGICALS LTD.) PUDUMUND POST/UDHAGAMANDALAM/HİNDİSTAN
ÇÖZÜCÜ ÜRETİM YERİ	:	SOVEREIGN PHARMA PVT. LTD. VİLLAGE KADAİYA/DAMAN/HİNDİSTAN
LİSANSÖR / ORİJİN FİRMA	:	HUMAN BIOLOGICALS INSTITUTE (A DIVISION OF INDIAN IMMUNOLOGICALS LTD.) PUDUMUND POST/UDHAGAMANDALAM/HİNDİSTAN
ÜRETİM YERİ	:	HUMAN BIOLOGICALS INSTITUTE (A DIVISION OF INDIAN IMMUNOLOGICALS LTD.) PUDUMUND POST/UDHAGAMANDALAM/HİNDİSTAN
PRİMER AMBALAJLAMA YERİ	:	HUMAN BIOLOGICALS INSTITUTE (A DIVISION OF INDIAN IMMUNOLOGICALS LTD.) PUDUMUND POST/UDHAGAMANDALAM/HİNDİSTAN
SEKONDER AMBALAJLAMA YERİ	:	HUMAN BIOLOGICALS INSTITUTE (A DIVISION OF INDIAN IMMUNOLOGICALS LTD.) PUDUMUND POST/UDHAGAMANDALAM/HİNDİSTAN MEFAR İLAÇ SAN. A.Ş. KURTKÖY-PENDİK/İSTANBUL
SERİ KONTROL ANALİZ YERİ İÇEREN SERİ SERBEST BIRAKMA YERİ	:	HUMAN BIOLOGICALS INSTITUTE (A DIVISION OF INDIAN IMMUNOLOGICALS LTD.) PUDUMUND POST/UDHAGAMANDALAM/HİNDİSTAN
RAF ÖMRÜ(AY)	:	36 AY
SAKLAMA SICAKLIĞI (^{0}C)	:	2-8 C ARASINDA BUZDOLABINDA
AMBALAJ TANIMI	:	KUTUDA, GRİ BROMOBUTİL KAUÇUK TIPALI, ALÜMİNYUM CONTALI, TOZ İÇEREN TİP I CAM FLAKON + ÇÖZÜCÜ İÇEREN 1 ML'LİK TİP I CAM AMPUL + 2 ML PLASTİK ENJEKTÖR (0,55X25 MM-24GX1-1 NOS İĞNELİ) + DEZENFEKSİYON MENDİLİ
AMBALAJ BOYUTU	:	1 FLAKON + 1 ÇÖZÜCÜ
RUHSAT HARCI	:	05.01.2018/12
ANALİZ HARCI	:	27.08.2015/162 16.11.2015/18515641840

Dr. Ali ALKAN
Kurum Başkan Yardımcısı

BỘ Y TẾ
MINISTRY OF HEALTH
CỤC QUẢN LÝ DƯỢC
DRUG ADMINISTRATION OF VIETNAM

CỘNG HÒA XÃ HỘI CHỦ NGHĨA VIỆT NAM
SOCIALIST REPUBLIC OF VIETNAM
Độc lập - Tự do - Hạnh phúc
Independence - Freedom - Happiness

GIẤY PHÉP LƯU HÀNH SẢN PHẨM
MARKETING AUTHORIZATION

Tên thuốc *Name of Drug:*		ABHAYRAB (Vắc xin phòng bệnh dại)
Thành phần chính, hàm lượng *Active Ingredients, Strength:*		Kháng nguyên tinh chế từ virus dại chủng L.Pasteur 2061 Vero 15 passage, nuôi cấy trên tế bào vero ≥ 2,5IU
Qui cách đóng gói, bào chế *Packing Size, Dosage form:*		Hộp 1 lọ vắc xin đông khô đơn liều + 1 lọ dung môi hoàn nguyên và 1 xy lanh vô trùng, Hộp 50 lọ vắc xin đông khô đơn liều+hộp 100 lọ dung môi hoàn nguyên vắc xin; Bột đông khô
Tiêu chuẩn chất lượng *Quality Specification:*	:	NSX
Hạn dùng *Shelf- life:*		36 tháng
Số giấy phép lưu hành sản phẩm (SĐK) *Marketing Authorization Number:*		QLVX-0305-14
Số quyết định *Approval Decision Number:*	:	576/QĐ-QLD Ngày cấp: 14/10/2014 *Date of Issuance:*
Hiệu lực của giấy phép lưu hành sản phẩm: có giá trị 05 năm kể từ ngày cấp *Expiration Date of this Marketing Authorization:*		
Tên cơ sở đăng ký *Name of Marketing Authorization Holder:*	:	Công ty cổ phần y tế Đức Minh
Địa chỉ *Address:*	:	Số 51, ngõ 205, ngách 323/83, đường Xuân Đỉnh, xã Xuân Đỉnh, huyện từ Liêm, Hà Nội - Việt Nam
Tên cơ sở sản xuất *Name of Manufacturer:*	:	Human Biologicals Institute (A division of Indian Immunologicals Limited)
Địa chỉ *Address:*	:	Kozhipannai, Pudumund P.O - Udhagamandalam - 643 007, Tamil Nadu - India
Tên cơ sở đóng gói *Name of Assembler:*	:	
Địa chỉ *Address:*	:	

Hà Nội, ngày 14 tháng 10 năm 2014.
CỤC TRƯỞNG CỤC QUẢN LÝ DƯỢC
GENERAL DIRECTOR OF THE DRUG ADMINISTRATION OF VIETNAM

TRƯƠNG QUỐC CƯỜNG

Ghi chú: *Note:*
1- Giấy phép lưu hành sản phẩm này được cấp theo đúng hồ sơ đăng ký trước đã được Bộ Y tế phê duyệt
This marketing authorization was granted strictly in accordance with the registration dossier approved by the Vietnam Ministry of Health
2- Bất cứ sự thay đổi nào về nội dung của giấy phép phải được Cục Quản lý dược - Bộ Y tế xác nhận
Any change of the content of this marketing authorization must be approved by the Drug Administration of Vietnam

All correspondence should be addressed to the Director General

DMS/7/9/22/PR/385

In reply please quote No.

PHARMACEUTICAL REGULATORY AUTHORITY

25th April 2013

Indian Immunologicals Ltd,
Road Number 44 Jubilee Hill,
Hyderabad 500 033,
India

Dear Sir/Madam,

RE: APPLICATION FOR REGISTRATION OF A PHARMACEUTICAL PRODUCT

Reference is made to your application for registration of a pharmaceutical product, submitted in terms 37 of the Pharmaceutical Act (No. 14) of 2004.

We wish to inform you that we have completed our review of the submission and are pleased to inform you that the Pharmaceutical Regulatory Authority considered your product application and the corresponding evaluation report and, based on the submitted information, **approved** the registration of the following product with its licence number and method of sale as indicated below:

No.	Name of Product	Application no.	Method of sale	Licence No.
1.	**ABHAYRAB VACCINE** (Inactivated Rabies antigen not less than 2.5IU per 0.5ml)	5175/08	POM	088/001

Abbreviation: POM– Prescription Only Medicine

Please note that approval is granted subject to your submission to the Authority as soon as possible, but not later than sixty days from the date of this letter, information and documents which were noted missing from your submissions on the following:

Certificates: - You are required to submit original copy of WHO-type certificate of Pharmaceutical product on for the above product specifically addressed to Zambia as well as the standards used in the analysis of the finished product. In addition, documentary evidence of registration in the declared countries (i.e. Turkey, Malawi, Philippines, Egypt, Kenya, Uzbekistan, Cambodia and Pakistan) should be provided.

Please note that a pre-shipment dully signed and dated lot release certificate issued by the competent authorities from the exporting country, will be required to accompany every consignment of this product destined for Zambia.

In addition, your attention is drawn to the requirements of Statutory Instrument No. 7 of 2008 on product retention fees for pharmaceutical products to be imported into Zambia. You are therefore requested to pay annual retention fees of ZMK 2,030,000-00 (ZMW 2,030.00) per product for the above products effective 1st January 2014. The amount due may be paid into the following bank account:

Head Office
Plot No. 6903 Turoleta Road-Off Makishi Road
P O Box [illegible] Lusaka, ZAMBIA
Telephone +260 211 240429 Telefax +260 211 238458
E-mail pharmacy@pra.gov.zm

Ndola Office
No. 41 Kafironda Drive Itawa
P O Box 70870
Telefax +260 212 610522

Website. www.pra.gov.zm

Report Adverse Reactions to:
Pharmacovigilance Unit Lusaka
Tel: +260 211 220080, 220089, 220106
E-mail: pharmacy@pra.gov.zm

Name of Account holder:	Pharmaceutical Regulatory Authority
Name of Bank:	Standard Chartered Bank, North-End Branch, Cairo Road, Lusaka, Zambia
ZMW Bank Account No.	0100122033800
US Dollar Account No.	8700211468100

Please note that registration of the above product does not imply final approval as all products are subject to review at a later date and this decision to register the above product is subject to change on the basis of new information that may be available to the Authority.

In view of this, you are advised to put in place an appropriate pharmacovigilance system for monitoring, detecting and reporting adverse drug reactions and the performance of registered products in general.

We wish to remind you that you must comply with labeling requirements as prescribed in the Statutory Instrument No 47 of 1993 by ensuring that products including labels and packaging materials have sufficient labelling information including among others; method of sale, specific storage conditions, product licence number and physical address of the manufacturing site.

If you have any questions, please do not hesitate to contact our Secretariat.

Yours faithfully,
for/**Pharmaceutical Regulatory Authority**

E Mwape (Ms)
DIRECTOR GENERAL

c.c. International Drug Company Limited, Lusaka, Zambia.

TELEPHONE: 3170585
FAX: 3170157
TELEGRAMS: RABONGAKA

REFERENCE:

Republic of Botswana

MINISTRY OF HEALTH
PRIVATE BAG 0038
GABORONE

REF NO. MH 15/37A VOL. III (1145)

23/04/2013

Regulatory Affairs Manager
Medivision (pty) Ltd, SA
20 Bowling ave.
Kramerville, Johannesburg. South Africa

Attention: REGULATORY PHARMACIST

Dear Officer,

RE: REGISTRATION OF MEDICINES

Your product which is listed below has been registered under the Drugs and Related Substances Act 1992 and the registration number is shown in the table below:

Name of the Product	Generic of the Product	Strength	Presentation	Application Number	Registration Number	Schedule	Approved Shelf-Life (in months)
Abhayrab-Rabies Vaccine B.P	Purified Vero Cell Rabies Vaccine	>2.5 IU / dose	0.5 mL Vial with lypholized powder	A0603176	BOT1202213	S2	24

A certificate of registration of the product listed above will be sent to you soon. Please acknowledge the receipt of this letter and give assurance that the Botswana registration number and schedule will be included in the package insert and label.

Please do not hesitate to contact the Drug Regulatory Unit at dunit@gov.bw if you have any questions.

Yours faithfully

Dr. K. Seipone

DIRECTOR OF HEALTH SERVICES

LA PREVOYANCE SOCIALE

DIRECTION DU MEDICAMENT
ET DE LA PHARMACIE

RÉPUBLIQUE GABONAISE
Union - Justice

Réf. : 100419
N° Enregistrement courrier /MSPP/CAB/DMP

Libreville, le 30 Juin 2014

Monsieur le Responsable des Laboratoires
INDIAN IMMUNOLOGICALS LTD
ROAD 44, Jubilee Hills
Hyderabad 500 033
INDIA

Monsieur,

J'ai l'honneur de vous informer que la **spécialité ABHAYRAB poudre lyophilisée pour injection IM/ID fl/0,5ml** a fait l'objet d'une Autorisation de Mise sur le Marché Gabonais **N°6952/14.**
Cette autorisation prend effet à compter du **30/06/2014** et sera valable jusqu'au **30/06/2019,** conformément aux dispositions de l'article 4 de l'arrêté n°1870/MSPP/GSP/SPH du 21 Décembre 1992 fixant les conditions d'obtention du visa d'enregistrement des produits pharmaceutiques en République Gabonaise.

Je vous prie d'agréer, Monsieur, l'expression de mes salutations distinguées.

Le Directeur du Médicament et de la Pharmacie

Sophie BIPOLO

P.J. : AMM N° 6952/14

MINISTERE DE LA SANTE ET DE
LA PREVOYANCE SOCIALE

REPUBLIQUE GABONAISE
Union - [illegible]

AMM N° 6952/14/DMP

Le Ministre de la Santé Publique

Vu la Constitution,

Vu la loi N° 70/61 du 11 Décembre 1961 modifiée par la loi 10/69 du 31 Décembre 1996 relative à l'exercice de la Pharmacie en République Gabonaise ;

Vu l'ordonnance 42 /PR du 18 Juin 1978 relative à la définition et à la commercialisation des médicaments en République Gabonaise ;

Vu l'ordonnance 01/95 du 14 janvier 1995 portant orientation de la politique de santé en République Gabonaise ;

Vu le décret 1445/PR/MSPP du 28 Novembre 1995 portant réglementation de l'importation, de la distribution et de la promotion des produits pharmaceutiques en République Gabonaise.

Vu le décret 1158/PR/MSPP du 4 Septembre 1997 fixant les attributions et organisation du Ministère de la Santé Publique et de la Population ;

Vu l'arrêté 1870/MSP/IGSP/SP du 21 Décembre 1992 fixant les conditions d'obtention de visa d'enregistrement des produits pharmaceutiques en République Gabonaise ;

La commission d'enregistrement des Produits Pharmaceutiques entendue,

DECIDE

Article 1er : Le visa prévu à l'article 2 et 5 de l'ordonnance 42/PR du 18 Juin 1978 est accordé à la spécialité dénommée **ABHAYRAB poudre lyophilisée pour injection IM/ID fl/0,5ml**

PGHT : 6.035FCFA

Exploitée par **INDIAN IMMUNOLOGICALS LTD** domicilié à l'adresse :
ROAD 44, Jubilee Hills
Hyderabad 500 033
INDIA

Répondant à la composition :
Principe Actif :
Vaccin antirabique B.P. : 2,5UI

Article 2 : Ce visa est valable cinq ans pour compter de sa date de signature

Article 3 : Le directeur du Médicament et de la Pharmacie est chargé de notifier la présente décision aux intéressés et partout où besoin sera.

Fait à Libreville, le 30/06/2014

P/ Le Ministre de la Santé Publique
P/ La Commission d'enregistrement et par délégation

Le Directeur du Médicament et de la Pharmacie

Sophie BIPOLO

MINISTERE DE LA SANTE ET
DE LA POPULATION

DIRECTION GENERALE DU MEDICAMENT
DE LA PHARMACIE ET DES LABORATOIRES

DIRECTION DE LA PHARMACIE ET
DU MEDICAMENT

B.P. : 1635 BRAZZAVILLE
E-mail : dirpharmcongo@yahoo.fr

REPUBLIQUE DU CONGO
Unité*Travail*Progrès

DECISION N° 15.123 /MSP/DGMPL/DPM-15

PORTANT HOMOLOGATION DE : ABHAYRAB, poudre lyophilisée de vaccin de la rage purifié pour injection IM ou ID, flacon de 0,5 ml

Le ministre de la santé et de la population

- Vu la Constitution
- Vu la loi n°54-418 du 15 avril 1954 étendant aux T.O.M, au Togo et au Cameroun, certaines dispositions du code de la santé publique relatives à l'exercice de la pharmacie ;
- Vu la loi n°006-94 du 1er juin 1994 portant réglementation des prix, des normes commerciales, de la constatation et répression des fraudes ;
- Vu le décret n° 2009-392 du 13 octobre 2009 relatif aux attributions du ministre de la santé et de la population
- Vu le décret n° 2012-1035 du 25 septembre 2012, portant nomination des membres du Gouvernement,
- Vu le décret n° 2013 - 813 du 30 décembre 2013 portant organisation du ministère de la santé ;
- Vu le décret n° 2013- 817 du 30 décembre 2013 portant attributions et organisation de la direction générale de la pharmacie, des laboratoires et du médicament ;
- Vu l'arrêté n° 634 /MSAS/DGSP/DPH.LM. du 26 avril 1992 fixant un certificat d'agrément des laboratoires pharmaceutiques

Sur proposition du directeur de la pharmacie et du médicament, Président de la Commission nationale des homologations ;

Après avis du directeur général du médicament, de la pharmacie et des laboratoires ;

DECIDE

Article premier :

Est accordée, après homologation, une autorisation de mise sur le marché du générique de marque : ABHAYRAB, vaccin antirabique, poudre lyophilisée en flacon de 0,5 ml

Article 2 :

Les références de l'autorisation de mise sur le marché sont :

- Code : VC PSM/MI-Vac/4.01.3 B/N°3 AHS2
- Titulaire : BHARAT SERUMS AND VACCINES LDT,
  17th Floor, Hoechst House,
  Nariman Point, Mumbai - 400 021, INDIA

- Site de fabrication et de libération des lots
  Human Biologicals Institute
  Division de Indian Immunologicals LTD
  Kozhipannai, Pudmund P.O.,
  Pin 643 007, Tamil Nadu, India

Article 3 :

La composition et le(s) indication(s) thérapeutique(s) sont respectivement les suivantes :

- Composition : Antigène purifié lyophilisé dérivé du virus de la rage
  Puissance > 2,5 U.I. par flacon
- Indication(s) thérapeutique(s) sont limitées à : vaccination préventive à l'exposition au virus pour les groupes de personnel à risque élevé : vétérinaires, travailleurs municipaux, personnel de santé, des eaux et forêts / vaccination post-exposition pour les personnes après un contact-morsure suspecte ou d'un animal enragé

Article 4 :

Le titulaire de l'autorisation de mise sur le marché s'est engagé à :

- informer le ministère de l'apparition de réactions secondaires ou accidents liés à la consommation de ABHAYRAB, vaccin antirabique dans les conditions normales d'utilisation, après l'obtention de l'AMM ;
- informer le ministère de toute(s) modification(s) ultérieure(s) de ABHAYRAB, vaccin antirabique dans un délai d'un (1) mois suivant la date de(s)dite(s) modification(s) ;