



MHRA
Regulating Medicines and Medical Devices

MHRA

151 Buckingham Palace Road
London SW1W 9SZ
United Kingdom

mhra.gov.uk

MR. P CHAKURKAR
KEY PHARMACEUTICALS LIMITED
GALEN HOUSE
83 HIGH STREET
SOMERSHAM
PE28 3JB
UNITED KINGDOM

22/06/2017

Dear Mr Chakurkar,

GRANT / RENEWAL OF MARKETING AUTHORISATION

Our Reference: PL 34424/0004 - 0001
Your Reference: 34424
Product: Celecoxib 200mg hard capsules
Type of Procedure: Decentralised
Submission Type: Initial
Submission Category: Abridged
EU Procedure Number (if applicable): UK/H/6239/002/DC

The Licensing Authority agrees to the grant or renewal of the marketing authorisation for the above submission on the basis of the data provided. This includes any replacement and amendment of the original dossier.

In line with Article 23a of Directive 2001/83/EC as amended, the Marketing Authorisation Holder should submit notification of the actual date of marketing of the product to the Competent Authority.
This notification should be provided by email to the following address: sunsetclause@mhra.gov.uk.

The formal documents are enclosed. These constitute evidence of authorisation. If you consider them to contain information that is incorrect or not in accordance with the dossier, please return immediately indicating any errors.

All Marketing Authorisations are subject to standard provisions contained in current medicines regulations full details of which are published on the MHRA website:

<http://www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Informationforlicenceapplicants/Provisionstowhichthemarketingauthorisationisgranted/index.htm>

Yours sincerely,

Keely Kennedy



MHRA
151 Buckingham Palace Road
London SW1W 9BS
United Kingdom
www.gov.uk

MR. P. CHAKRABARTY
KEY PHARMACEUTICALS LIMITED
GALLEN HOUSE
83 HIGH STREET
BIRMINGHAM
B2 2JL
UNITED KINGDOM

22/09/2017

Dear Mr. Chakraborty,

GRANT / RENEWAL OF MARKETING AUTHORIZATION

Our Reference: [blank]
Your Reference: [blank]
Product: [blank]
Type of Product: [blank]
Submission Type: [blank]
Submission Category: [blank]
EMA Reference: [blank]



The following information is provided for the grant or renewal of the marketing authorization for the above submission on the basis of the information provided in your submission and any information and documents submitted to the MHRA website.

In line with Article 10(1) of Directive 2001/83/EC, the Marketing Authorization Holder shall submit a declaration of the product to the Competent Authority. This declaration shall be provided by email to the following address: marketing@mhra.gov.uk.

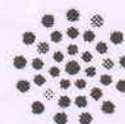
The format documents are included. These contain a range of information. If you consider them to contain information that is incorrect or not in accordance with the facts, please contact us immediately indicating any errors.

All Marketing Authorizations are subject to standard provisions contained in current legislation and to the extent of which are published on the MHRA website.

The above information is provided for the grant or renewal of the marketing authorization for the above submission on the basis of the information provided in your submission and any information and documents submitted to the MHRA website.

Yours sincerely,

Keep Records



MHRA
Regulating Medicines and Medical Devices

The Human Medicines Regulations SI 2012/1916, as amended.

GRANT / RENEWAL OF MARKETING AUTHORISATION

Product: PL 34424/0004 - 0001 Celecoxib 200mg hard capsules
Submission Type: Initial

Granted to: KEY PHARMACEUTICALS LIMITED
GALEN HOUSE
83 HIGH STREET
SOMERSHAM
PE28 3JB
UNITED KINGDOM

This Marketing Authorisation, under the above reference number is hereby granted / renewed in respect of the product named above. The Summary of Product Characteristics of the product is set out in the attached document.

The application is subject to the further provisions set out or referred to in the above Regulations.

This Marketing Authorisation, as now granted / renewed, unless previously revoked, will continue in force until the expiry date (if applicable) given below.

Grant Date: 22/06/2017

Date of Expiry: 25/05/2022

Keely Kennedy

A person authorised to sign on behalf of the Secretary of State for Health

PL 34424/0004 - 0001

Medicines and Healthcare
Products Regulatory Agency

भारत सरकार GOVERNMENT OF INDIA
अपोस्टिल / APOSTILLE
(Convention de La Haye du 5 octobre 1961)
INDIA

This public document of the type
COMMERCIAL DOCUMENT

is issued to KEY PHARMACEUTICALS LTD.

has been signed by SUBHADRA NAIR

with the seal / stamp of SECRETARY, RAIGAD CHAMBER OF
COMMERCE AND INDUSTRY, MUMBAI

Certified by
Section Officer(OI) MINISTRY OF EXTERNAL AFFAIRS
on 30-Jun-2017 at NEW DELHI, INDIA

with reference no. MHMC0021291217

Signature
(देबब्रता पॉल)
(DEBABRATA PAUL)
अनुभाग अधिकारी (ओ.आई.)
Section Officer (O.I.)
सी.पी.वी. प्रभाग/C.P.V. Division
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs
New Delhi



For Raigad Chamber of Commerce & Industry

12.9 JUN 2017

Subhadra Nair
Secretary