DR. RAM MANOHAR LOHIA INSTITUTE OF MEDICAL SCIENCES
VIBHUTI KHAND, GOMTI NAGAR, LUCKNOW-10(U.P)
Phone No : - 0522-4918502, 4918510

Ref No: 153/HRF/PAC/2026 Dated: 06 March . 2026

Notice

Sub:- Procurement of following items on proprietary/ single quotation basis for different department

The Dr. RMLIMS, Lucknow intend to procure following item (s) manufactured as per mentioned against item name for **Brigatinib 30mg, 90 and 180mg film coated tablets** on proprietary/ single quotation basis from their authorized dealer/ seller as per enclosed Technical Specifications.

Sl no	Product details	Principle Company (Manufacturer)	Subsidiary Company (Marketing)	Authorised Seller/ Company/Dealer
1	**Brigatinib 30mg, 90 and 180mg film coated tablets (Brand Name:- Alunbrig)**	M/s Takeda Ireland Limited, Bray Business park, Kilruddery co. Wicklow (Ireland)-A98CD36	M/s Takeda Biopharmaceuticals India Pvt. Ltd, Khasra No-1/24, Hasanapur, Gurugram,Haryana (India)-122004	M/s D. N. Associates India Pvt. Ltd, Lucknow, UP

The Proprietary Certificate for above items (s) submitted by principle company or their authorized seller/ Company/ Dealer is attached. The above documents are being uploaded for open information to all manufacturer/ supplier to submit comments / objections/ representation to submit comments/surgical/medicine items within 10 working days to the chairmen. (HRF), Dr RMLIMS, Lucknow on email id hrftendercell@gmail.com, from the date mentioned above, falling which it will be presumed that no other supplier is having any comment to offer and the case will be decided on merits. The comments/objection/representation to be submitted on the following:-

(i) Weather the above medicine/surgical items is manufactured by any other manufacture other than as per mentioned principle company or their Authorized seller/company/Dealer.

(ii) Fulfill all the parameter(s) as per technical specifications.

Encl: - Related documents enclosed.

(1) HRF Requisition form
(2) PAC Certification of company letter.
(3) Authorization from company letter.

Chairman (HRF)
Dr. RMLIMS, Lucknow

HRF
12/3/26

HRF Requisition Form

Request for new items/upgraded version

(Drugs, Consumables & Disinfectants)

('X' if is not applicable)

1. Name of item (generic name only, no brand name)... BRIGATINIB 30mg/90mg/180mg .....

   Please note that if another brand of the same item is already available in HRF, the request will not be entertained for another brand.

2. Quantity needed (Per month) ..... 10 Boxes .....
3. Probable Source (I) ..... Takeda Biopharmaceuticals Ltd. .....

   (II) .....

   (III) .....

   (If only one source please sign. The P-3 Form on back page)

4. Similar item available In HRF inventory? -Yes/~~No~~
5. If yes then, why this item? .....

   .....

6. Do you want this item to be made available on regular basis -Yes/No
7. If yes, then what will be the monthly consumption of this item? ..10 Boxes....
8. Is same item in single unit be used on many patients ? If yes then specify the Number of times/Number of patients, the unit will be used..... NA .....
9. Will it be a part of any procedure (Dossier, please specify the name of procedure..... NA .....
10. If it is an upgraded version of an existing item in HRF inventory, do you want old version to continue? - -Yes/~~No~~
11. Justification for new requisition... Newly available drug in India with metastatic ALK+ NSCLC patients .....

12/3/26

AO HRF

13/3/26

As CMAC

13/3/26

Dr. Amit Pandey
Assistant Professor Medical Oncology Dr. RMLIMS, Lko.
MBBS, MD,DM (Medical Oncology)
FICR SCE (UK), ESMO Certified
Monday/ Friday

(Sign. of Consultant)

DR. SOHAM BHUSHANA SETHI
MD, MAMS, FCRO
Professor, Radiation Oncology
HOD, Medical Oncology
Dr. R.M.L.I.M.S., Lucknow

(Signature of Head of Department)

Please note that new item will be processed for short-term rate contract- this may take about 1-2 months time.

FORM P-3

Dr. Ram Manohar Lohia Institute of Medical Sciences, Lucknow

PROPRIETARY ARTICLE CERTIFICATE

It is certified that the items required should be purchased from M/s. TAKEDA BIOPHARMACEUTICALS LTD. Who are the sole manufacture/agents of the sole manufacturers M/s D.N ASSOCIATES INDIA PVT. LTD.

Similar items manufactured by other firm(s) shall not be suitable for our purpose for the following reasons: -

Newly available drug in India with metastatic ALK + NSCLC

Dr. Amit Pandey
Assistant Professor Medical Oncology
MBBS, MD (KGMU), DM (Medical Oncology)
MRCP (UK), EDRO (EU)

Signature of Indenter

Requisition No:
Department :
Dated :

Designation &
Sign of Head of
Department/ Section

Dr. ROHINI KHURANA SETHI
MD, MAMS, FICRO
Professor, Radiation Oncology
HOD, Medical Oncology
Dr. R.M.L.I.M.S., Lucknow

N.B. The Indenter before recording the above certificate should satisfy himself that the article is genuinely of proprietary nature manufactured under patent laws.

Subject: Proprietary Article Certificate
From: Takeda Ireland Limited – Bray
Reference: QA-REG-2025-052

13th June 2025

This is to certify that molecule: Brigatinib 30 Mg, 90 and 180 mg Film Coated Tablets (Brand name: Alunbrig®) is a registered trademark of M/s. Takeda Pharmaceuticals U.S.A., Inc.

Takeda Biopharmaceuticals India Private Limited (formerly known as Baxalta Bioscience India Private Limited) located at 6th Floor, Tower 8C, DLF Cyber City, Phase – II, Gurgaon, Haryana, India is authorized to Import and market the molecule: "Brigatinib 30 Mg, 90 and 180 mg Film Coated Tablet (Brand name: Alunbrig®)", in India by way of duly valid regulatory approvals/ License.

Details of said molecule is mentioned below.

Name of the molecule:	Brigatinib 30 Mg, 90 and 180 mg Film Coated Tablets
Brand Name	Alunbrig
Dosage form:	Film Coated Tablets

Sincerely,

James Dinniss
Director
Takeda Ireland Limited
Bray Business Park,
Kilruddery,
Co. Wicklow,
Ireland. A98 CD36

13-June-2025
Date

Takeda Ireland Limited
Bray Business Park
Kilruddery
Co Wicklow
Ireland
A98 CD36

PATRICK JONES
1, EGLINTON ROAD,
BRAY, CO. WICKLOW.
NOTARY PUBLIC
COMMISSIONED FOR LIFE

File no: IMP/Form8/FF/2025/39387

Directorate General of Health Services
Office of Drugs Controller General (India)
(Import & Registration Division)

FDA Bhawan, Kotla Road
New Delhi-110002
Phone No-011-23236965
Fax: 23236973
Date: 19-03-2025

To

M/s Takeda Biopharmaceuticals India Pvt. Ltd.,
Khasra No. 1/24, 25, 3/1/1, Gala No. 1A-1F, 2A-2E, 3B-3E And 4A-4E
Warehouse No. 1, Sector-76, Hasanpur Darbaripur
Gurugram, Haryana (India) - 122004

Sub: Import Licence under the Drugs and Cosmetics Act and Rules thereunder.

Dear Sir/Sirs,

With reference to your application for import licence forwarded to this office, I enclose licence(s) No. **IL/FF-000872 - RC/FF-002375** dated **19-03-2025**. This/These licence(s) has/have been issued under the Drugs and Cosmetics Act and Rules thereunder.

1. I am to point out the provisions of Drugs and Cosmetics Act are in addition to and not derogation of any other law for the time being in force and as such the licences issued under Drugs and Cosmetics Act will be in addition to and distinct from any licences which may be necessary under the Import Trade Control Regulations made of the Government Of India, Ministry of Commerce.

2. The import licence(s) mentioned in para(I) above will not accordingly to itself/themselves be sufficient authority for import of Drugs covered by that/those licence if under the Import Trade Control Regulations of the Commerce Ministry separate licences are required for import of such drug(s).

3. I am therefore, to advise you to obtain, where necessary licences for import of drugs in question under the Import Trade Control Regulations.

4. Any literature or packing accompanying the drug or any matter stated on the label should not contravene the provisions of the Drugs and Magic Remedies(Objectionable Advertisement) Act.

5. The Assistant Drugs Controller (India) and Technical Officer of the Central Organization at the ports will be Officers Authorized to inspect the premises of importers establishments for the purpose of Rule 26 of the Drugs & Cosmetics Rules.

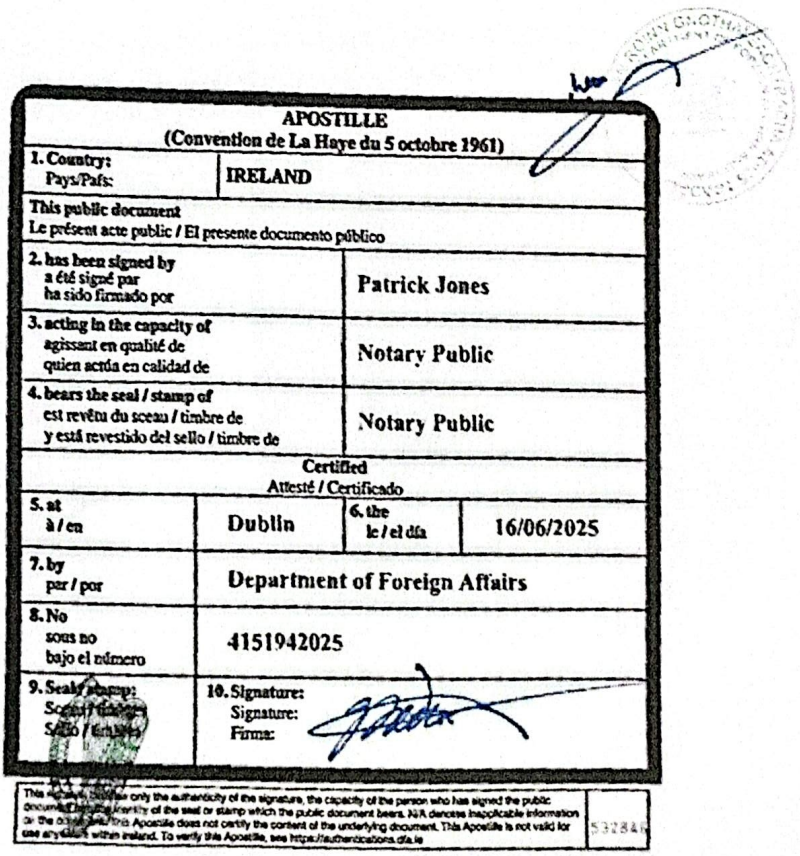
6. Please acknowledge receipt of this letter and its enclosures.

LICENSING
AUTHORITY

RAJEEV SINGH RAGHUVANSHI

Scanned with CamScanner

S.No - IMP/Form8/FF/2025/39387
Copy along with copy of License No. IL/FF-000872 - RC/FF-002375
To All Port Offices.



APOSTILLE
(Convention de La Haye du 5 octobre 1961)

1. Country: Pays/Pafs:	IRELAND
This public document Le présent acte public / El presente documento público	
2. has been signed by a été signé par ha sido firmado por	Patrick Jones
3. acting in the capacity of agissant en qualité de quien actúa en calidad de	Notary Public
4. bears the seal / stamp of est revêtu du sceau / timbre de y está revestido del sello / timbre de	Notary Public

Certified
Attesté / Certificado

5. at à / en	Dublin	6. the le / el día	16/06/2025
7. by par / por	Department of Foreign Affairs		
8. No sous no bajo el número	4151942025		
9. Seal / stamp: Sceau / timbre Sello / timbre	10. Signature: Signature: Firma:		

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