Date: 17th April, 2023

To,
The Manager,
Department of Corporate Services,
BSE Limited
P. J. Towers, Dalal Street,
Fort, Mumbai – 400 001
BSE Scrip Code: 533573

To,
The Manager,
Listing Department,
National Stock Exchange of India Ltd.
'Exchange Plaza', Bandra Kurla Complex,
Bandra (E), Mumbai – 400 051
NSE Symbol: APLLTD

Dear Sir/Madam,

Sub: Revision in Company's practice for making disclosures for product approvals.

Over the last few years, the Company had consistently but voluntarily followed a practice of making disclosures to the stock exchanges for each product approval (Tentative or Final) received from US Food & Drug Administration (USFDA).

Most of such disclosures were not falling within the purview of the Company's Policy for Determination of Materiality ("Materiality Policy") framed in terms of the criteria prescribed in Regulation 30(4) of SEBI (Listing Obligation and Disclosure) Regulation, 2015 ("Listing Regulations"). At the time, when such practice was adopted, the Company and the industry in general had lower number of products in pipeline for approval, whereas, now such approvals have become a routine affair.

In view of the various recent regulatory developments, including SEBI's press release dated 29th March, 2023 read with SEBI's Consultation Paper dated 12th November, 2022 to revise the disclosure requirements for material events, the persons authorized under the Company's Materiality Policy have decided to change the practice followed by the Company for making disclosures for product approvals and henceforth provide disclosures for only such product approvals which fall within the purview of the statutory requirements.

However, on voluntary basis, the Company will file a summary of all product approvals received during the previous quarter for information of general investors. One such summary statement giving brief of all product approvals received during January-March 2023 quarter is enclosed for your information and records.

We request you to kindly take the above on record.

Thanking you,

Yours faithfully,
For Alembic Pharmaceuticals Limited

MANISHA SARAF
Digitally signed by MANISHA SARAF
Date: 2023.04.17 13:10:22 +05'30'

Manisha Saraf
Company Secretary

Encl: A/a.

Annexure

Summarised Product Approval received during the quarter ended 31st March, 2023.

Product Name	Approval Final/ Tentative	Innovator Name	Brand name	Indication*
Fesoterodine Fumarate Extended-Release Tablets, 4 mg and 8 mg	Final	Pfizer Inc	Toviaz ER Tablets	Fesoterodine fumarate extended-release tablets are indicated for the treatment of overactive bladder (OAB) in adults with symptoms of urge urinary incontinence, urgency, and frequency
Acalabrutinib capsules 100mg	Tentative	Astrazeneca UK ltd	Calquence Capsules	Acalabrutinib Capsules are indicated for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy and treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)
Docetaxel Injection USP, 20 mg/2 mL (10 mg/mL) Single-Dose Vial, and 80 mg/8 mL (10 mg/mL) and 160 mg/16 mL (10 mg/mL) Multiple-Dose Vials	Final	Hospira Inc	Docetaxel injection	Docetaxcel injections are indicated for the breast cancer, non-small cell lung cancer, castration-resistant prostate cancer, gastric adenocarcinoma and squamous cell carcinoma of head and neck
Fluorouracil Injection USP, 2.5 g/50 mL (50 mg/mL) Pharmacy Bulk Vial	Final	Spectrum Pharmaceuticals, Inc	Fluorouracil Injection	Fluorouracil Injection is indicated for the treatment of patients with adenocarcinoma of colon and rectum, adenocarcinoma of the breast, gastric

Product Name	Approval Final/ Tentative	Innovator Name	Brand name	Indication*
				adenocarcinoma and pancreatic adenocarcinoma
Prazosin Hydrochloride Capsules USP, 1 mg, 2 mg, and 5 mg	Final	Pfizer Inc	Minipress Capsules	Prazosin hydrochloride capsule is indicated for the treatment of hypertension, to lower blood pressure
Brexpiprazole Tablets, 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg and 4 mg	Tentative	Otsuka	Rexulti Tablets	Brexpiprazole tablets are indicated as an adjunctive therapy to antidepressants for the treatment of major depressive disorder and for treatment of schizophrenia. It may not be indicated for certain other uses due to unexpired exclusivities for the RLD for such uses.
Brimonidine Tartrate Ophthalmic Solution, 0.15%	Final	AbbVie Inc	Alphagan P Ophthalmic Solution	Brimonidine Tartrate Ophthalmic Solution is an alpha adrenergic receptor agonist indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension

*Refer label for full indication.