

29 June, 2021

The Manager – Listing
BSE Limited,
1st Floor, New Trading Ring
Rotunda Building, P J Towers, Dalal Street, Fort,
Mumbai 400001

The Manager – Listing
National Stock Exchange of India Ltd.
Exchange plaza, 5th Floor, Plot No.C/1, G Block
Bandra-Kurla Complex, Bandra (E),
Mumbai 400051

Dear Sir(s),

Intimation pursuant to Regulation 30 of SEBI (Listing Obligation and Disclosure Requirements) Regulations, 2015, pertaining to notice of demand from National Pharmaceutical Pricing Authority

Ref: Scrip Code - BSE: 506820 / NSE: ASTRAZEN

This is to inform that the Company has received a notice of demand on 25th June 2021 from National Pharmaceutical Pricing Authority ('NPPA') under the provisions of Drugs (Price Control) Order, 2013 (DPCO, 2013) in respect of Tagrisso tablets containing Osimertinib 80 mg formulation.

The said notice of demand has been issued pursuant to the NPPA notification S.O No. 1041 (E) dated 27th February 2019 whereby, the Government put a cap on trade margin of 42 anti-cancer medicines at first point of sale of the product.

The said notice of demand alleges that the Company is in violation of notification S.O No. 1041 (E) dated 27th February 2019, and has overcharged Rs. 157,38,85,007/- (Rupees One hundred fifty seven crore thirty eight lakh eighty five thousand and seven only) during the period from 8th March 2019 to 31st January 2021 in respect of Tagrisso (Osimertinib) 80 mg tablets. Consequently, the Company has been ordered to deposit an amount Rs. 157,38,85,007/- within 30 days from the date of the notice.

It is further stated in the said notice of demand that the Company is also liable to pay interest, calculated up to the date of actual payment as per the applicable provisions of the DPCO, 2013 read with the Essential Commodities Act, 1955.

The Company strongly believes that the NPPA has not adequately considered several submissions made in support of the Company's contentions, including the fact that Osimertinib is a patented drug and as such the DPCO, 2013 and the said notification dated 27th February 2019 are not applicable to Osimertinib as comprehended under Para 32 of the DPCO, 2013.

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The Company has carried out a thorough evaluation of the matter and is of the firm view that it has followed all applicable laws related to pricing of its product, including the said notification S.O No. 1041 (E) dated 27th February 2019 and that the above demand from the NPPA is grossly erroneous and legally unsustainable

The Company is committed to provide best access to its drugs through its patient assistance programs which directly benefit patients who pay out-of-pocket by helping them access drugs free of cost if enrolled successfully in such programmes. The NPPA's order may have Industry wide implications on patient assistance programs and consequently affordability of medicines for out-of-pocket patients.

Additionally, the notice penalises the Company for supplying at lower rate to government institutions vide tenders as compared to MRP and yet for purposes of accounting erroneously included the MRP and not the amount actually realized.

Considering the above, the Company has filed a Writ Petition before the Hon'ble High Court of Delhi challenging the demand notice.

While the notice was received on 25th June 2021, some time was spent in good faith for the evaluation of the demand notice and of the Company's legal position against the demand. We request you to accordingly take the above submission on your records.

Thanking you,

For AstraZeneca Pharma India Limited

Pratap Rudra
Company Secretary & Legal Counsel