

October 17, 2017

The Manager- Listing  
**BSE Limited**  
Corporate Relationship Dept., 5<sup>th</sup> Floor, New Trading Ring  
Rotunda Building, P J Towers, Dalal Street, Fort,  
Mumbai - 400001

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

Dear Sir(s),

**Sub: AstraZeneca Pharma India Limited receives Import and Market Permission in Form 45 (Marketing Authorization) from Drug Controller General of India (DCGI) for FDC of Dapagliflozin + Metformin Hydrochloride (extended release) 5mg / 500mg, 5mg / 1000mg, 10mg / 500mg & 10mg / 1000mg film coated tablets.**

This is to inform that AstraZeneca Pharma India Limited has received Import and Market Permission in Form 45 (Marketing Authorization) from the Drug Controller General of India for FDC of Dapagliflozin + Metformin Hydrochloride (Extended Release) film coated tablets (XIGDUO XR<sup>®</sup>).

The FDC of Dapagliflozin + Metformin Hydrochloride (Extended Release) film coated tablets (XIGDUO XR<sup>®</sup>) is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both dapagliflozin and metformin is appropriate.

*Please find attached a copy of News Release dated October 17, 2017 being issued by AstraZeneca Pharma India Limited in connection with the above.*

Kindly take the same on record.

Thanking you,

For AstraZeneca Pharma India Limited

  
**Pratap Rudra**  
Company Secretary & Legal Counsel



### **AstraZeneca India receives marketing approval for XIGDUO XR®, a novel combination of two anti-diabetic therapies for type 2 diabetes**

**Bengaluru, 17<sup>th</sup> October 2017:** Leading global biopharmaceutical company AstraZeneca Pharma India Limited (AstraZeneca India) has received Marketing Authorisation from the Drug Controller General of India (DCGI), for XIGDUO XR®, a once-daily tablet (fixed dose combination of SGLT2 inhibitor – dapagliflozin and metformin hydrochloride extended release) for the treatment of adults with type 2 diabetes in India. XIGDUO XR® is indicated as an adjunct therapy to diet and exercise to improve glycemic control in adults with type 2 diabetes, when treatment with both dapagliflozin and metformin is appropriate.

XIGDUO XR® is a product of the AstraZeneca Group has been approved in 61 countries to date including US, EU and Japan and continues to demonstrate an overall favorable benefit risk profile for treatment of patients with type 2 diabetes.

Dapagliflozin belongs to a new class of type 2 diabetes medication, SGLT2 (a highly selective inhibitor of sodium-glucose cotransporter 2). It has a unique insulin independent mode of action that helps in improving glycaemic control with added benefits of weight loss and blood pressure reduction. Dapagliflozin and Metformin have complementary mechanism of action with clinically important effects in maintaining blood glucose levels. The metformin XR component decreases hepatic glucose production and increases peripheral glucose uptake and utilization, while the SGLT2 inhibitor aids in glucose elimination via renal excretion.

**Dr. Anilda Dsouza, Head – Medical Affairs & Regulatory, AstraZeneca India said,** “XIGDUO XR® will provide physicians and patients with an advanced treatment option that provides better glycemic control, potential weight loss and the reduced risk of hypoglycemia. Type 2 diabetes is a growing epidemic in India, affecting more than 65 million patients<sup>1</sup> and is associated with significant comorbidities often requiring more than a monotherapy to achieve glycemic control. With XIGDUO XR® we are able to offer physicians a personalized and effective treatment option to manage this chronic and progressive disease”

XIGDUO XR® is approved with multiple dosage strengths of dapagliflozin and metformin hydrochloride extended-release, respectively, including 5 mg/500 mg, 5 mg/1000 mg, 10 mg/500 mg, and 10 mg/1000 mg, and the starting dose can be individualized based on each patient’s current treatment regimen. It is not recommended for patients with type 1 diabetes mellitus or diabetic ketoacidosis.

AstraZeneca India has a broad non-insulin anti-diabetic product portfolio and offers products in novel and fast-growing classes of diabetes treatments - Dipeptidyl Peptidase-4 (DPP-4) inhibitors and SGLT-2 inhibitor.

<sup>1</sup> <http://www.diabetesatlas.org/across-the-globe.html>



## About AstraZeneca

AstraZeneca is a global, science-led biopharmaceutical company that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of diseases in three main therapy areas - Oncology, Cardiovascular & Metabolic Diseases and Respiratory. The Company also is selectively active in the areas of autoimmunity, neuroscience and infection. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information, please visit [www.astrazeneca.com](http://www.astrazeneca.com) and follow us on Twitter @AstraZeneca.

## About AstraZeneca Pharma India Limited (AstraZeneca India)

AstraZeneca India was established in 1979 and is headquartered at Bengaluru, Karnataka. AstraZeneca India has a workforce of over 1100 employees across the country that is committed to deliver great medicines to patients in three crucial areas of healthcare – cardiovascular metabolic diseases, respiratory and oncology. For more information, please visit: [www.astrazeneca.com/india](http://www.astrazeneca.com/india)

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