Dr. Reddy's Laboratories Ltd.
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April 23, 2024

National Stock Exchange of India Ltd. (Scrip Code: DRREDDY-EQ)
BSE Limited (Scrip Code: 500124)
New York Stock Exchange Inc. (Stock Code: RDY)
NSE IFSC Ltd. (Stock Code: DRREDDY)

Dear Sir/Madam,

Sub: Press Release

Please find enclosed a Press Release on **"Dr. Reddy's issues voluntary nationwide recall of Sapropterin Dihydrochloride Powder for Oral Solution 100 mg due to Sub-potency".**

This is for your information and records.

Thanking you.

Yours faithfully,
For **Dr. Reddy's Laboratories Limited**

KUMAR RANDHIR SINGH
Digitally signed by KUMAR RANDHIR SINGH
Date: 2024.04.23 20:14:43 +05'30'

K Randhir Singh
Company Secretary, Compliance Officer & Head-CSR

Press Release

Dr.Reddy's

DR. REDDY'S LABORATORIES LTD.
8-2-337, Road No. 3, Banjara Hills,
Hyderabad - 500034. Telangana, India.

CONTACT	
INVESTOR RELATIONS	**MEDIA RELATIONS**
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Dr. Reddy's issues voluntary nationwide recall of Sapropterin Dihydrochloride Powder for Oral Solution 100 mg due to Sub-potency

FOR IMMEDIATE RELEASE Hyderabad India and Princeton, NJ, US; April 23, 2024 – Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY, NSEIFSC: DRREDDY, along with its subsidiaries together referred to as "Dr. Reddy's"), today announced that it is voluntarily recalling six (6) lots of Sapropterin Dihydrochloride Powder for Oral Solution 100 mg to the consumer level due to powder discoloration in some packets leading to decreased potency. The issue was discovered during an accelerated stability test in addition to customer complaints.

Risk Statement: Reduced efficacy of the product would result in elevated Phenylalaninemia (Phe) levels in patients. Chronically elevated Phe levels in infants and children are likely to cause permanent neurocognitive deficits, including permanent and irreversible intellectual disability, developmental delay, and seizures. Furthermore, elevated Phe levels during pregnancy, especially in early gestation, are associated with microcephaly and congenital heart disease.

Dr. Reddy's Laboratories Inc. has not received any reports of adverse events related to this recall to date.

The product is indicated to reduce blood phenylalanine (Phe) levels in adult and pediatric patients one month of age and older with hyperphenylalaninemia (HPA) due to tetrahydrobiopterin-(BH4-) responsive Phenylketonuria (PKU) and is packaged in individual packets, 30 per carton. The affected Sapropterin Dihydrochloride Powder for Oral Solution 100mg lots include the following:

Product Name	Lot Number	Expiration date	NDC Number
Javygtor™ (Sapropterin Dihydrochloride) Powder for Oral Solution 100 mg	T2202812	07/2025	43598-097-30
	T2204053	10/2025	43598-097-30
	T2300975	02/2026	43598-097-30
	T2300976	02/2026	43598-097-30
	T2304356	08/2026	43598-097-30
Sapropterin Dihydrochloride Powder for Oral Solution 100 mg	T2200352	12/2024	43598-477-30

Sapropterin Dihydrochloride Powder for Oral Solution 100 mg was distributed nationwide to wholesalers/retailers.

KUMAR RANDHIR SINGH

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Date: 2024.04.23 20:15:33 +05'30'

Dr. Reddy's Laboratories Inc. is notifying its distributors and customers by recall notification letters and is arranging for returns of all recalled products. Anyone with an existing inventory of the product being recalled should examine the product and quarantine any of the recalled lots immediately. Consumers who have Sapropterin Dihydrochloride Powder for Oral Solution 100 mg which is being recalled should contact their physician before stopping use of the product. Consumers who have Sapropterin Dihydrochloride Powder for Oral Solution 100 mg which is being recalled should return it to their place of purchase.

Consumers with questions regarding this recall can contact Dr. Reddy's Laboratories Inc. by calling 866-733-3952 during office hours from 9 a.m. to 5 p.m. (EST) Monday through Friday. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

Please click here to see the full prescribing information for Sapropterin Dihydrochloride Powder for Oral Solution 100 mg.

RDY-0424-639

About Dr. Reddy's: Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY, NSEIFSC: DRREDDY) is a global pharmaceutical company headquartered in Hyderabad, India. Established in 1984, we are committed to providing access to affordable and innovative medicines. Driven by our purpose of 'Good Health Can't Wait', we offer a portfolio of products and services including APIs, generics, branded generics, biosimilars and OTC. Our major therapeutic areas of focus are gastrointestinal, cardiovascular, diabetology, oncology, pain management and dermatology. Our major markets include – USA, India, Russia & CIS countries, China, Brazil and Europe. As a company with a history of deep science that has led to several industry firsts, we continue to plan ahead and invest in businesses of the future. As an early adopter of sustainability and ESG actions, we released our first Sustainability Report in 2004. Our current ESG goals aim to set the bar high in environmental stewardship; access and affordability for patients; diversity; and governance. For more information, log on to: www.drreddys.com.