Bill No. 68 of 2024

THE GLUCOTEST STRIPS (REGULATION AND PRICE CONTROL) BILL, 2024

By

SHRI SHRIRANG APPA BARNE, M.P.

A

BILL

to ensure uniformity and standardization in the manufacturing, distribution, and pricing of glucotest strips across India with a view to improve diabetes management and ensure affordability of glucotest strips for all and for matters connected therewith.

Whereas diabetes is a chronic condition affecting a significant portion of the population in India;

AND WHEREAS regular monitoring of blood glucose levels is essential for effective diabetes management;

AND WHEREAS glucotest strips are a crucial component in the monitoring process;

AND WHEREAS there is a need to ensure uniformity, affordability, and accessibility of glucotest strips for all individuals,

BE it enacted by Parliament in the Seventy-fifth Year of the Republic of India as follows:—

Short title, extent and commencement.

- 1. (1) This Act may be called the Glucotest Strips (Regulation and Price Control) Act, 2024.
 - (2) It extends to the whole of India.

(3) It shall come into force on such date as the Central Government may, by notification in the Official Gazette, appoint.

Definitions.

- 2. In this Act, unless the context otherwise requires,—
 - (a) "distributor" means any company engaged in the distribution of glucotest strips;

5

10

15

20

2.5

30

35

45

- (b) "glucotest strip" means a strip used in a glucometer to measure blood glucose level in the human body;
- (c) "manufacturer" means any company engaged in the production of glucotest strips; and
 - (d) "prescribed" means prescribed by rules made under this Act.

Uniform Standards for Glucotest Strips.

- **3.** (1) The Central Government shall, within six months of the commencement of this Act, prescribed uniform standards for the manufacturing and quality of glucotest strips in the country.
- (2) The standards under sub-section (I) shall include specifications for accuracy, reliability and safety of the glucotest strips in such manner as may be prescribed.

Licensing and Compliance.

- **4.** (1) No person shall manufacture or import glucotest strips without a valid license issued by the authority prescribed in this behalf by the Central Government.
- (2) The authority prescribed under sub-section (1) shall ensure compliance with the standards set forth under section 3.
- (3) The Central Government shall conduct regular inspection and audits of the manufacturers and distributors to ensure compliance of the provisions of this Act.

Regulation of Prices.

- 5. (1) The Central Government shall, by notification in the Official Gazette, establish a Committee to regulate and monitor the prices of glucotest strips in the country in such manner as may be prescribed.
- (2) The composition of and other terms and conditions of the Committee shall be such as may be prescribed.
- (3) The Committee shall determine the price of glucotest strips and ensure that the prices are fair, affordable and uniform across the country in such manner as may be prescribed.

Restraint on Sale of glucotest strips at prices exceeding MRP. **6.** No manufacturer and distributor shall sell glucotest strips at prices exceeding the maximum retail price determined by the Committee.

Subsidies and Support for Low-Income Groups.

- 7.(1) The Central Government shall introduce schemes to subsidize the cost of glucotest strips for low-income groups in the country in such manner as may be prescribed.
- (2) The public healthcare facilities including hospitals and clinics shall provide glucotest strips at subsidized rates or free of cost to the persons living below poverty line as may be determined by the Central Government, from time to time.

Penalties.

8. Any person who manufactures, distributes or sell glucotest strips in contravention of the provisions of this Act shall be liable to a fine which may extend to five lakh rupees and in case of repeated offence, the person shall be liable to imprisonment for a term which may extend to one year and with fine which may extend to fifteen lakh rupees.

Offence by Companies.

9. Where an offence under this Act has been committed by a company, every person who, at the time the offence was committed, was in charge of, and was responsible to, the

company for the conduct of the business shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly.

10. The Central Government shall, after due appropriation made by Parliament by law in this behalf, provide adequate funds for the implementation of the provisions of the Act.

5

10

15

20

Central Government to provide funds.

11. (1) If any difficulty arises in giving effect to the provisions of this Act, the Central Government may, by order, published in the Official Gazette, make such provisions not inconsistent with the provisions of this Act as may appear to be necessary for removing the difficulty:

Power to Remove diffculties.

Provided that no order shall be made under this section after the expiry of two years from the commencement of this Act.

- (2) Every order made under this section shall be laid, as soon as may be after it is made, before each House of Parliament.
- **12**. (*1*) The Central Government may, by notification in the Official Gazette, make rules for carrying out the provisions of this Act.

Power to make

(2) Every rule made under this section shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session for a total period of thirty days which may be comprised in one session or in two or more successive sessions and if, before the expiry of the sessions immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule of both Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule.

STATEMENT OF OBJECTS AND REASONS

The price of glucose test strips in India exhibits significant variation due to multiple factors such as brand, quality, availability, distribution channels, and regional economic conditions. Typically, the cost of glucose test strips ranges from ₹300 to ₹1,500 for a pack of 50 strips, but this can fluctuate based on several key determinants.

Firstly, brand reputation plays a crucial role in pricing. Established brands like Accu-Chek, OneTouch, and Dr. Morepen generally command higher prices due to their perceived reliability and widespread recognition. These brands often invest heavily in research and development, ensuring accuracy and consistency in their products, which justifies the premium pricing. Conversely, lesser-known or generic brands offer more affordable options, though they may lack the same level of trust and reliability among consumers.

Secondly, the quality and features of the test strips impact their cost. Strips that offer advanced features such as faster reading times, smaller blood sample requirements, and compatibility with mobile apps or data management systems tend to be priced higher. These features cater to users looking for convenience and more integrated health management solutions.

Availability and distribution channels also influence prices. In urban areas with numerous pharmacies and healthcare providers, competition can drive prices down. However, in rural or remote areas where access to medical supplies is limited, prices might be higher due to logistical challenges and reduced competition. Online marketplaces like Amazon and Flipkart often offer competitive pricing and discounts, potentially lower than brick-and-mortar stores, due to reduced overhead costs and bulk purchasing advantages.

Regional economic conditions and government policies further affect pricing. States with better healthcare infrastructure and higher purchasing power may see lower prices due to economies of scale and better supply chain management. Additionally, government initiatives to make healthcare more affordable, such as subsidies or price controls on essential medical supplies, can also help in stabilizing or reducing the cost of glucose test strips.

Therefore, this Bill aims to address the disparities in the availability and pricing of glucotest strips across India. By establishing uniform standards, regulating prices, and providing subsidies to low-income groups, the Bill seeks to make diabetes management more accessible and affordable. The increasing prevalence of diabetes necessitates such measures to ensure the well-being of the affected population.

Hence, this Bill.

New Delhi;

SHRIRANG APPA BARNE

July 8, 2024.

FINANCIAL MEMORANDUM

Clause 5 of the Bill provides for the establishment of a Committee to regulate and monitor the prices of glucotest strips in the country. Clause 10 of the Bill provides for the Central Government to provide necessary funds for carrying out the purpose of this Act. The Bill, therefore, if enacted and brought into operation will involve expenditure from the Consolidated Fund of India. It is estimated that a sum of rupees two thousand crore, may be involved as recurring expenditure per annum.

Non recurring expenditure to the tune of rupees two thousand crore may also involve from the Consolidated Fund of India.

MEMORANDUM REGARDING DELEGATED LEGISLATION

Clause 12 of the Bill empowers the Central Government to make rules for carrying out the purposes of this Bill. As the rules will relate to matters of details only, the delegation of legislative power is of a normal character.

LOK SABHA

A

BILL

to ensure uniformity and standardization in the manufacturing, distribution, and pricing of glucotest strips across India with a view to improve diabetes management and ensure affordability of glucotest strips for all and for matters connected therewith.