AS INTRODUCED IN THE RAJYA SABHA
ON THE 7TH FEBRUARY, 2025

Bill No. VII of 2025

THE MEDICINES AND MEDICAL DEVICES (PRICE CONTROL AND ACCESSIBILITY) BILL, 2025

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BILL

to provide for the establishment of an Authority to regulate the prices of all medicines and medical devices, including implants and medical equipments, in the country to ensure fair and reasonable pricing, thereby safeguarding the interests of patients, especially the poor and marginalized sections of society, while fostering an ethical and transparent healthcare system and for matters connected therewith or incidental thereto.

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

Short title and commencement.

1. *(1)* This Act may be called the Medicines and Medical Devices (Price Control and Accessibility) Act, 2025.

(2) 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) "Authority" means the National Pharmaceutical Price Control Authority established under section 3 of this Act;

(b) "Division" means the Monitoring and Enforcement Division established under section 8 of this Act;

(c) "Interim Pharmaceutical Pricing Authority" means the National Pharmaceutical Pricing Authority constituted by the Central Government through Resolution No. 33/7/97 PI, dated 29th August, 1997;

(d) "maximum retail price" means the highest permissible selling price set by the Authority, inclusive of all taxes, beyond which no sale of the medicine or medical device may occur;

(e) "medical device" means any instrument, apparatus, appliance, implant, or other equipment used for the treatment, diagnosis, or monitoring of medical conditions;

(f) "medicine" means any drug or pharmaceutical product available for human consumption for treatment, prevention, or diagnosis of diseases;

(g) "Member" means a Member of the Authority and includes the Member-Secretary and Advisors;

(h) "prescribed" means prescribed by rules made under this Act; and

(i) 'price control' means the regulatory mechanism through which the price of medicines and medical devices is determined and controlled to prevent arbitrary pricing.

Establishment and incorporation of the National Pharmaceutical Price Control Authority.

3. *(1)* With effect from such date as the Central Government may, by notification, appoint, there shall be established, for the purposes of this Act, an Authority to be called the National Pharmaceutical Price Control Authority.

(2) The Authority shall be a body corporate by the name aforesaid, having perpetual succession and a common seal, with power to acquire, hold, and dispose of property, both movable and immovable, and to contract, and shall, by the said name, sue or be sued.

(3) The head office of the Authority shall be at New Delhi.

(4) The Authority may establish offices at other places in India.

Composition of the Authority.

4. *(1)* The Authority shall consist of the following Members, namely,–

(a) a Chairperson, to be appointed by the Central Government, who shall hold a status equivalent to that of a Secretary to the Government of India;

(b) such number of whole-time Members, as may be prescribed, having expertise in the fields of pharmaceuticals, economics, or cost accountancy;

(c) a Member Secretary, who shall be a Joint Secretary or Additional Secretary to the Government of India; and

(d) such number of Advisors, not exceeding seven, as may be prescribed:

Provided that each Advisor shall be an officer of the Government of India not below the rank of Joint Director.

(2) The salary and allowances payable to, and other terms and conditions of service of, the Members, other than Member Secretary and Advisors, shall be such as may be prescribed.

(3) The Authority may appoint such officers and other employees as it considers necessary for the efficient discharge of its functions under this Act.

(4) The terms and other conditions of service of officers and other employees of the Authority appointed under sub-section (3) shall be such as may be prescribed.

Transfer of assets, liabilities, etc., of Interim Pharmaceutical Pricing Authority.

5. On and from the date of establishment of the Authority,—

(a) all the assets and liabilities of the Interim Pharmaceutical Pricing Authority shall stand transferred to, and vested in, the Authority.

Explanation.—The assets of the Interim Pharmaceutical Pricing Authority shall be deemed to include all rights and powers, all properties, whether movable or immovable, including, in particular, cash balances, deposits and all other interests and rights in, or arising out of, such properties as may be in the possession of the Interim Pharmaceutical Pricing Authority and all books of account and other documents relating to the same; and liabilities shall be deemed to include all debts, liabilities and obligations of whatever kind;

(b) without prejudice to the provisions of clause (a), all debts, obligations and liabilities incurred, all contracts entered into and all matters and things engaged to be done by, with or for the Interim Pharmaceutical Pricing Authority immediately before that day, for or in connection with the purpose of the said Authority, shall be deemed to have been incurred, entered into or engaged to be done by, with or for, the Authority;

(c) all sums of money due to the Interim Pharmaceutical Pricing Authority immediately before that day shall be deemed to be due to the Authority; and

(d) all suits and other legal proceedings instituted or which could have been instituted by or against the Interim Pharmaceutical Pricing Authority immediately before that day may be continued or may be instituted by or against the Authority.

Functions of the Authority.

6. *(1)* The Authority shall implement and enforce the provisions of the Drugs (Prices Control) Order, 2013 in accordance with the powers delegated to it under the Essential Commodities Act, 1955 and the Drugs and Cosmetics Act, 1940.

10 of 1955.
23 of 1940.

(2) Without prejudice to the generality of the functions referred to in sub-section *(1)*, the Authority may perform all or any of the following functions, namely, to:—

(i) regulate the prices of medicines and medical devices, recognizing their classification as essential commodities under the Essential Commodities Act, 1955, and the Drugs and Cosmetics Act, 1940, and to ensure their affordability and availability to the public;

10 of 1955.
23 of 1940.

(ii) ensure that all medicines, including generic, patented, and over-the-counter drugs, and all medical devices, implants, and equipment used for treatment, diagnosis, or monitoring, are subject to the price control regime established under this Act;

(iii) determine the maximum retail price of medicines and medical devices based on the cost of production, distribution, and a reasonable

profit margin, while taking into account their necessity and affordability for economically disadvantaged sections of society;

(iv) mandate the display of the maximum retail price on the packaging of all medicines and medical devices in the manner prescribed and to ensure transparency and compliance with this requirement;

(v) review, at least annually or as deemed necessary, the prices of medicines and medical devices, and to make adjustments to such prices in view of changes in production costs, raw material availability, or other relevant factors to maintain fairness and accessibility;

(vi) monitor compliance with the price control regime established under this Act by all manufacturers, distributors, and retailers, and to take enforcement actions against violations in the manner prescribed;

(vii) undertake research and analysis on pricing trends, affordability, and availability of medicines and medical devices in the country and to provide recommendations to the Central Government on policy measures to enhance accessibility and affordability of essential medical commodities; and

(viii) perform such other functions as may be assigned to it by the Central Government or as may be necessary to carry out the provisions of this Act.

Responsibility of manufacturers and retailers regarding compliance and transparency.

7. *(1)* Every manufacturer shall ensure that all compliance reporting concerning the production, pricing, and sale of medicines and medical devices is carried out electronically through the system established by the Authority and made accessible to the public *via* the official website of the Authority.

(2) Every retailer, including pharmacies, medical outlets, and healthcare establishments, shall,–

(a) issue a sale invoice for each transaction involving the sale of medicines or medical devices;

(b) upload the sale invoice to the website of the Authority, excluding any patient name or other personally identifiable information, to ensure privacy;

(c) include the name of the prescribing doctor on each invoice to enable the effective monitoring of prescription practices.

(3) The Authority shall ensure that the online compliance system established under sub-section *(1)* is operational and accessible for monitoring the compliance with the maximum retail prices across various retail outlets, thereby preventing arbitrary pricing and minimizing opportunities for corruption.

(4) Every manufacturer shall submit to the Authority the Price-to-Retailer information for each medicine and medical device as part of the compliance reporting requirement, and such information shall be made publicly accessible on the website of the Authority to allow the public to understand the pricing structure and profit margins associated with the maximum retail prices of medicines and medical devices.

Explanation.– For the purpose of this sub-section, 'Price-to-Retailer' shall mean the wholesale price at which a manufacturer sells a medicine or medical device to a retailer.

8. *(1)* The Authority may, for the effective implementation of the provisions of this Act, establish a Monitoring and Enforcement Division, which shall be vested with such powers and responsibilities as may be prescribed. Monitoring and Enforcement Mechanisms.

(2) The Division shall be responsible for overseeing and ensuring compliance with the pricing regulations and maximum retail price requirements under this Act.

(3) The Division shall conduct regular audits and inspections of manufacturers, distributors, and retailers to ensure their compliance with the provisions of this Act, including the pricing and maximum retail price requirements.

(4) Any manufacturer, distributor, or retailer found in violation of the price control regulations under this Act shall be liable to penalties, which may include the suspension of licenses and imposition of fines, as prescribed under section 9 of this Act.

(5) The Authority may prescribe, by regulations, the composition, powers, and functions of the Division and such other matters as may be necessary for the efficient discharge of its duties under this Act.

9. *(1)* Any manufacturer, distributor, or retailer who contravenes the pricing regulations or maximum retail price requirements under this Act shall be liable to imprisonment for a term which may extend up to three years, or to a fine which may extend up to ten lakh rupees or both. Penalty.

(2) In the case of repeat violations, the Authority may, in addition to the penalty specified in sub-section *(1)*, revoke the licenses of the manufacturer, distributor, or retailer permanently, thereby prohibiting them from manufacturing, distributing, or selling medicines and medical devices within the country.

10. *(1)* 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 of the company, as well as the company shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly: Offences by companies**.**

Provided that nothing contained in this sub-section shall render any such person liable to any punishment provided in this Act if he proves that the offence was committed without his knowledge or that he exercised all due diligence to prevent the commission of such offence.

(2) Notwithstanding anything contained in sub-section *(1)*, where an offence under this Act has been committed by a company and it is proved that the offence has been committed with the consent or connivance of, or is attributable to any neglect on the part of, any director, manager, secretary or other officer of the company, such director, manager, secretary or other officer shall also be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

Explanation.--For the purposes of this section—

(a) "company" means a body corporate, and includes a firm or other association of individuals; and

(b) "director" in relation to a firm means a partner in the firm.

11. (*1*) The Central Government shall, after due appropriation made by Parliament by law in this behalf, pay to the Authority by way of grants, such sums of money as it may consider necessary for carrying out the purposes of this Act. Grants by the Central Government.

(*2*) The Authority may spend such sums, as it thinks fit, for performing the functions assigned to it under this Act, and such sums shall be treated as expenditure payable out of the grants referred to in sub-section (*1*).

Accounts and audit.

12. (*1*) The Authority shall, in consultation with the Comptroller and Auditor-General of India, maintain proper accounts and other relevant records and prepare an annual statement of accounts in such form and manner and at such time of each financial year, as may be prescribed.

(2) The accounts of the Authority shall be audited by the Comptroller and Auditor-General at such intervals as may be specified by him and any expenditure incurred in connection with such audit shall be payable by the Authority to the Comptroller and Auditor-General.

(3) The Comptroller and Auditor-General and any person appointed by him in connection with the audit of the accounts of the Authority under this Act shall have the same rights and privileges and the authority in connection with such audit as the Comptroller and Auditor-General generally has in connection with the audit of Government accounts and, in particular, shall have the right to demand the production of books, accounts, connected vouchers and other documents and papers and to inspect any of the offices of the Authority.

(4) The accounts of the Authority, as certified by the Comptroller and Auditor-General or any other person appointed by him in this behalf, together with the audit report thereon shall be forwarded annually to the Central Government by the Authority.

Annual report.

13. The Authority shall prepare, in such form and at such time, for each financial year, as may be prescribed, its annual report, giving a full account of its activities during the previous financial year and forward a copy thereof to the Central Government.

Annual report and audit report to be laid before Parliament.

14. The Central Government shall cause the annual report together with the audit report, to be laid, as soon as may be after the reports are received, before each House of Parliament.

Power to make rules and regulations.

15. *(1)* The Central Government may, by notification in the Official Gazette, make rules for carrying out the purposes of this Act.

(2) The Authority may, with the previous approval of the Central Government, make regulations not inconsistent with this Act and the rules made thereunder for the purpose of giving effect to the provisions of this Act.

(3) Every rule and every regulation made under this Act 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 session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or 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.

Power to remove difficulties.

16. *(1)* If any difficulty arises in giving effect to the provisions of this Act, the Central Government may, by order, not inconsistent with the provisions of this Act, remove the difficulty:

Provided that no such order shall be made after the expiry of such period as may be prescribed from the date of commencement of this Act.

(2) Every order made under this section shall, as soon as may be after it is made, be laid before each House of Parliament.

Savings.

17. Anything done or any action taken by the Interim Pharmaceutical Pricing Authority and Central Government under the Resolution No. 33/7/97 PI, dated the 29th August, 1997, shall be deemed to have been done or taken under the corresponding provisions of this Act.

STATEMENT OF OBJECTS AND REASONS

Currently, only around 25 per cent. of medicines in the Indian market are regulated under a price control regime, leaving the remaining 75 per cent, subject to arbitrary pricing by manufacturers. This results in inflated Maximum Retail Prices (MRPs) that significantly burden patients, particularly those from economically disadvantaged backgrounds. Recognizing the essential nature of medicines and medical devices, this Bill is proposed to bring all such products under a fair and reasonable price control regime, ensuring accessibility and affordability for all.

2. Under the Essential Commodities Act, 1955 read with its Schedule and the Drugs and Cosmetics Act, 1940, every medicine and medical device is classified as an essential commodity. This classification imposes a responsibility on the Central Government to ensure their equitable distribution and availability at fair prices. This Bill envisions a comprehensive pricing framework under the supervision of the National Pharmaceutical Pricing Control Authority (NPPCA), to replace the National Pharmaceutical Pricing Authority (NPPA), which is already functioning in the domain of drug pricing, making it a suitable authority to set and enforce MRPs for all medicines and medical devices.

3. The NPPCA, an established statutory regulatory authority, will be tasked with setting MRPs and enforcing fair pricing across all medicines and medical devices. By leveraging the NPPA's expertise and infrastructure, this Bill seeks to streamline price regulation, prevent arbitrary pricing, and curb exploitative practices in the healthcare market. The NPPCA will periodically review and adjust MRPs to reflect changes in production costs and market conditions, ensuring that essential healthcare products remain accessible to all sections of society.

4. To enhance transparency and accessibility, this Bill mandates that all compliance by manufacturers be reported online and displayed on the NPPCA's website. Medical sale outlets and healthcare establishments are also required to issue and upload sale invoices, including the prescribing doctor's name while maintaining patient confidentiality. This online reporting and monitoring system will allow for real-time tracking of pricing practices, supporting regulatory oversight across a vast number of medical outlets and reducing corruption.

5. The objectives of this Bill are to:

(a) establish a comprehensive and equitable price control regime for all medicines and medical devices by utilizing the regulatory authority of the NPPCA;

(b) prevent arbitrary and exploitative pricing practices that place a financial burden on patients, particularly from marginalized sections;

(c) ensure transparency in the pricing structure of essential healthcare commodities, enabling public access to fair pricing information; and

(d) require compliance through online reporting, fostering accountability across the healthcare supply chain.

6. The Medicines and Medical Devices (Price Control and Accessibility) Bill, 2025, will benefit the country by:

(a) ensuring that essential medicines and medical devices are priced fairly, supporting the financial well-being of patients.

(b) protecting economically disadvantaged and marginalized communities from price exploitation in healthcare.

(c) enhancing public trust in the healthcare sector by fostering transparency in pricing.

(d) empowering the NPPCA to monitor, review, and adjust MRPs in alignment with market dynamics and production costs.

Hence, this Bill.

SHAKTISINH GOHIL

FINANCIAL MEMORANDUM

Clause 3 of the Bill provides for the establishment of National Pharmaceutical Pricing Control Authority as a statutory body, including the appointment of the Chairperson and other members, the staff of the Authority, their salaries, and other allowances, as well as the conditions of service of the Chairperson, members, and staff. Clause 11 provides that the Central Government shall make grants of such sums of money to the Authority, as it may consider necessary, to enable it to carry out the purposes of the Bill.

The Bill, therefore, if enacted, would involve both non-recurring and recurring expenditure from the Consolidated Fund of India. However, at this juncture, it is difficult to estimate the actual expenditure likely to be involved.

MEMORANDUM REGARDING DELEGATED LEGISLATION

Clause 15 empowers the Central Government and the Authority to make rules and regulations respectively to carry out the provisions of this Bill. Clause 16 provides that the Central Government may, make such order or give such direction, as necessary for removing any difficulty to give effect to the provisions of this Bill.

As the rules, regulations, orders or directions will relate to matters of details only, the delegation of legislative power is of a normal character.

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to provide for the establishment of an Authority to regulate the prices of all medicines and medical devices, including implants and medical equipments, in the country to ensure fair and reasonable pricing, thereby safeguarding the interests of patients, especially the poor and marginalized sections of society, while fostering an ethical and transparent healthcare system and for matters connected therewith or incidental thereto.

(Shri Shaktisinh Gohil, M.P.)

RS-P&PS—PMB(E)—105-10.02.2025