IN THE HIGH COURT OF MADHYA PRADESH

AT JABALPUR

WP No. 12 of 2015

(AMITABH GUPTA Vs *UNION OF INDIA AND OTHERS)*

Dated : 21-02-2025

Shri Amitabh Gupta petitioner in person.
None for respondents.

ORDER

By way of this writ petition, the petitioner has sought the following reliefs:-

> *"(i) The respondent No. 3 to include the chemical/reagents/salts/kits used by the Pathological Lab for diagnosis of a disease in the Pharmacopoeia and prescribe/prepare monograph/formulary fixing the identity, purity, and strength therefore as per the requirement of Section 16 of the Drugs and Cosmetics Act, 1940 and Rule 124 of the Drugs and Cosmetics Rules, 1945.*
> *(ii) The respondent No. 2, 4, 5, 6 and 7 to conduct tests/verification of the chemical/reagents/salts/kits manufactured in India as well as imported to India, as per the monograph/formulary prescribed by the respondent No. 3.*
> *(iii) The respondent No. 1 & 8 to ensure in a phased manner that no chemical/reagents/salts/kits is being used by the Pathological Labs in the other states of the country as well as in the State of M.P. except those manufactured as per the standards prescribed by the respondent No. 3.*

(iv) The respondent No. 1 and 8 to take necessary steps in a phased manner to ensure that every pathological Lab running in the territory is accredited to respondent No. 9.
(v) The respondent No.1&8 to take necessary steps to ensure that no manufacturer should manufacture nor any Importer should Import any chemical/reagents/salts/kits to be used in Pathological Labs except of the standards prescribed by the respondent No.3 and verified by the respondent No. 4,5 and 6.
(vi) The respondents to furnish report before the Hon'ble Court with respect to the steps taken by them in relation to the aforementioned reliefs sought by the Petitioner in a phased manner till the provisions of the Act as well as the Rules are complied with in toto.
(vii) Any other relief which the Hon'ble Court deems fit in the facts and circumstance of the case."

(2) The reply filed by the respondents No. 1,2 ,4 and 5 is on record whereby it is stated that the Drugs and Cosmetics Act, 1940 (Act hereinafter) along with the Drugs and Cosmetics Rules, 1945 (Rules herein after), made there under is a legislation with an objective to regulate the import, manufacture, distribution and sale of drugs and cosmetics while preventing the spurious, adulterated and substandard drugs to be imported, manufactured, distributed and sold in the country. The avowed objective of the Act is to ensure the safety, efficacy and the quality of the drugs being imported, manufactured, distributed and sold in the

country. Section 16 of the Act mentions about standard of quality and the same is reproduced hereunder:

> 16. **Standards of quality**.—(1) For the purposes of this Chapter, the expression "standard quality" means—
> (a) in relation to a drug, that the drug complies with the standard set out in the Second Schedule, and
> (b) in relation to a cosmetic, that the cosmetic complies with such standard as may be prescribed.

(3) That in reply to the contents of paragraph Nos. 3.4 to 3.8, it has been stated by the respondents that Indian Pharmacopoeia Commission is an autonomous institution under the Ministry of Health and Family Welfare, Government of India. It deals with matters relating to timely publication of the Indian Pharmacopoeia which is the official book of standards for drugs, in terms of the second schedule of the Drugs and Cosmetics Act, 1940 so as to specify the standards of identity, purity and strength for the drugs imported, manufactured for sale, stocked or exhibited for sale or distributed in India. With the above objective in view, the Indian Pharmacopoeia Commission (IPC) was registered as a society under the Societies Registration Act, 1860 under the Ministry of Health and Family Welfare, with the mandate to perform, inter alia, functions such as revision and publication of the

Indian 'Pharmacopoeia and the National Formulary of India on a regular basis.

(4) It is further stated that Section 16 of the Act mentions about standard of quality and the same is reproduced hereunder:

> 16. Standards of quality.—{1) For the purposes of this Chapter, the expression "standard quality" means—
> (a) in relation to a drug, that the drug complies with the standard set out in the Second Schedule, and
> (b) in relation to a cosmetic, that the cosmetic complies with such standard as may be prescribed.

(5) It is stated that Rule 124 of the Act mentions about Standards of Drugs included in Indian Pharmacopoeia and for other drugs. Drugs are to conform to the standard prescribed in the IP for the time being in force and its immediately preceding editions as the case may be. It is respectfully submitted the monographs of chemicals/reagents/salts/kits used in the Pathological laboratory do not pertain to mandate of Indian Pharmacopoeia Commission.

(6) It is further stated that drugs has been defined under section 3(b) of the Drugs and Cosmetics Act, 1940 and the same is reproduced here under:

> Section 3(b) "drug" includes—
> (i) all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes;

(ii) such substances other than food intended to affect the structure or any function of the human body or intended to be used for the destruction of vermin or insects which cause disease in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette;
(iii) all substances intended for use as components of a drug including empty gelatine capsules; and
(iv) such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Board;

(7) It is further stated that as per the definition of drugs under section 3(b)(iv) of the Drugs and Cosmetics Act, 1940, only those reagents and kits notified by the Central Government in the Gazette which are used for diagnosis of disease and disorders are covered and regulated under the Act. It is further submitted that only three diagnostic kits/ device that is HbsAg, HCV and HIV are notified and regulated for import and manufacture. Other non-notified diagnostic kits are regulated as a drug by virtue of them falling under the definition of drugs as defined under section 3(b)(i). It is further submitted that laboratory chemicals, salts and reagents for laboratory analysis are not regulated under the provisions of Drugs and Cosmetics Act.

2. That the In-Vitro Diagnostics Medical Devices are defined as drugs under Drugs & Cosmetics Act vide section 3(b)(i) and 3(b)(iv) which reads as;

> Section 3(b) —drug includes
> (i) all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquit oes;]
> (iv) such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Board.

The import, manufacturing, sale and distribution of such products are regulated as per the provision of said Act and Rules made thereunder. As per the definition of drugs under section 3(b) (i) of Drugs and Cosmetics Act 1940, all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals are regulated under the provisions of Drugs and Cosmetics Act 1940 and Medical Devices Rules 2017.

Other laboratories chemicals, salts, reagents used for laboratory analysis not intended for In-vitro Diagnosis purpose are not regulated under the provision of Drugs and Cosmetics Act 1940 and Medical

Devices Rules 2017. In this regard MDR-2017 was published vide Gazette notification vide G 5. 3/400) dated 31st January, 2017 effective from First January 2018 which stated the standards of Medical Devices including In-Vitro Diagnostics Medical Devices;

Rule 7, Product standards for medical device —

> (1) The medical device shall conform to the standards laid down by the Bureau of Indian Standards established under section 3 of the Bureau of Indian Standards Act, 1985 (63 of 1985) or as may be notified by the Ministry of Health and Family Welfare in the Central Government, from time to time.
> (2) Where no relevant Standard has been laid down under sub-rule (1), such device shall conform to the standard laid down by the International Organisation for Standardisation (ISO) or the International Electro Technical Commission (IEC), or by any other pharmacopoeial standards.
> (3) In case of the standards which have not been specified under sub-rule (1) and sub-rule (2), the device shall conform to the validated manufacturer's standards.

This means that operator/ manufacturer has to follow available Indian/ International standards or use their own validated standards.|

Indian Pharmacopeia Commission (IPC) and Bureau of Indian Standard (BIS) have their own procedure for standards development and for putting or deleting them from standards list wherein they publish standards for Drugs, Devices, and Cosmetics.

When IPC, BIS etc. are having their systematic committee to add or delete the standards, the request to include standard of reagent/ chemical etc. which are the laboratory grade, analytical grade and various other grade reagent and solution used by the user based on their experience and recommendation of Instruction for use (IFU) of manufacturer and to attach criminal or civil liability for not following such standards is not warranted and may create a situation of over regulation and lack of access to diagnostics in the country.

Further, which specific reagents, chemicals etc. need standards is also not specified by petitioner (like water, HCI, NaCl etc. or other). Therefore, it is quite general proposition and it may be appropriate to leave it to standard setting bodies to take up such issues and if there are any specific requirement this should be first forwarded to them by the petitioner with justification.

(8) It is stated that to ensure the quality and performance of Medical Devices Including In-vitro Diagnostic Medical Devices under the provisions of Rule 19 of MDR-2017

> (1) The Central Government may, by notification, establish Central medical devices testing laboratory for the Purpose of,—
> (a) testing and evaluation of medical devices; or
> (b) functioning as an appellate laboratory; or

(c) to carry out any other function as may be specifically assigned to it.
(2) Without prejudice to sub-rule (1), the Central Government may also designate any laboratory having facility for Carrying out test and evaluation of medical devices as central medical devices testing laboratory for the purposes specified in sub-rule (1):

To ensure Quality and competency of laboratories no medical devices testing laboratory, shall be so designated unless it has been duly accredited by the National Accreditation Body for Testing and Calibration Laboratories (NABL).

In pursuance of power conferred under sub-rule 2 of rule 19 of MDR- 2017, the Central Government vide Gazetted notification S.O. 2237(E) dated 1st June 2018 has designated the following laboratories as Central Medical Device testing laboratory for the purpose stated in the rule 19 of MDR-2017.

Sr.No.	Name of Laboratory	Category of Medical Device
(1)	(2)	(3)
1	The National Insitute of Biologicals Noida	In – Vintro Diagnostics for human Immunodeficiency virus, Hepatitis B Surface Antigen and Hepatitis C Virus Blood Grouping sera, Glucose Test Strip. Fully Automated Analyser Based Glucose Reagent.
2	The Central Drug Testing Laboratory, Chennai	Condoms
3	The Central Drugs Laboratory, Kolkata	Surgical Dressing, Surgical Cotton, Surgical Bandages, Disinfectant
4.	The Regional Drugs Testing Laboratory (RDTL), Guwahati	Disposable Hypodermic Syringes. Disposable Hypodermic Needle, Disposable Perfusion Sets. LV Cannulae.
5	The Central Drugs Testing Laboratory, Mumbai	Intra Uterine Devices (IUD) and Falope Rings.

The above designated laboratories are duly accredited by the National Accreditation Body for Certification Laboratories (Respondent No.9).

(9) The respondent/State has adopted the return filed by the respondent Nos. 1,2,4 and 5. Since the steps have been taken and in view of the return filed by the respondents mentioned above, we hereby direct as under:

(a) The Union of India is directed to file an affidavit mentioning the list of all the chemicals/regents/salts/kits etc used in pathological labs for diagnostic purposes and whether Indian Pharmacopoeia (Respondent No.3) has provided monograph / formulary regarding identity, purity and strength of such chemical etc.

(b) The respondent No.3 shall also file an affidavit mentioning whether it has provided monograph/ formulary regarding identity, purity and strength of such chemicals, etc and if not, then what is the feasibility for providing such standards.

(c) The respondents/Union of India and Authorities of State of Madhya Pradesh are directed to provide list of pathological labs accredited to NABL within the State of Madhya Pradesh and in what manner they will ensure that every pathological lab running in State of Madhya Pradesh is accredited to respondent No.9. They

will also initiate steps to ensure that such laboratories are accredited to respondent No.9 in phased manner and shall intimate the steps taken for enforcing accreditation of Pathological laboratories with NABL.

The aforesaid be carried out within a month. Matter be posted for further consideration in the week commencing 01.04.2025.

(SURESH KUMAR KAIT)
CHIEF JUSTICE

(VIVEK JAIN)
JUDGE

praveen