KARNATAKA LEGISLATIVE ASSEMBLY
SIXTEENTH LEGISLATIVE ASSEMBLY
EIGHTH SESSION

THE DRUGS AND COSMETICS (KARNATAKA AMENDMENT) BILL, 2025

(LA Bill No. 71 of 2025)

A Bill to amend the Drugs and Cosmetics Act, 1940 (Central Act 23 of 1940) in its application to the State of Karnataka.

Whereas, it is expedient to amend the Drugs and Cosmetics Act, 1940(Central Act, 23 of 1940) in its application to the State of Karnataka for the purposes hereinafter appearing;

Be it enacted by the Karnataka State Legislature in seventy sixth year of the Republic of India as follows: -

1. Short title and commencement.- (1)This Act may be called the Drugs and Cosmetics (Karnataka Amendment) Act, 2025.

(2) It shall come in to force on such date as the state Government may, by notification, appoint.

2. Amendment of section 6.- In the Drugs and Cosmetics Act, 1940 (Central Act 23 of 1940) (hereinafter referred to as the Principal Act), in section 6, in sub-section (1), after the proviso, the following proviso shall be inserted, namely:-

"Provided further that the State Government may, with the prior approval of the Central Government, direct that the functions of the Central Drugs Laboratory and of the Director in respect of drugs or cosmetics may be carried out in Karnataka by such authority and such officer respectively as may be specified by the State Government by notification in the Official Gazette, and any reference in this Act to the Central Drugs Laboratory or the Director shall then be construed as a reference to such Authority or officer, as the case may be."

3. Insertion of section 19A.- In the Principal Act, after section 19, the following new section shall be inserted, namely:-

"**19A. Burden of proof.-** when any drug or cosmetic is seized from any person in the reasonable belief that such drug or cosmetic is misbranded or adulterated, the burden of proving that such drug or cosmetic is not misbranded or adulterated shall be on the person from whose possession such drug or cosmetic was seized."

4. Amendment of section 30.- In the Principal Act, in section 30,-

(a) in sub-section (1), in clause (a),for the words "ten years", the words "imprisonment for life", shall be substituted;

(b) in sub-section (1A), for the words " which may extend to two years, or with fine which may extend to two thousand rupees, or with both.", The words "which shall not be less than two years but which may extend to imprisonment for life and shall also be liable to fine", shall be substituted.

5. Substitution of section 32.- For section 32 of the Principal Act, the following shall be substituted, namely:-

"**32. Cognizance of offences and arrest without warrant**.—(1) all offences punishable under this Act shall be cognizable and non-bailable.

(2) Any police officer not below the rank of a sub-inspector of Police may assist the drug inspector by whom a reasonable complaint has been made or Creditable information has been given of his having been contravened in any of the offences punishable under this Act."

6. Amendment of section 33.- In the Principal Act, in section 33, after sub-section(1), the following shall be inserted, namely:-

"(1A) The State Government may, by notification in the Official Gazette and subject to the condition of previous publication, make rules to, prescribe the fees payable, wherever applicable, and of any other additional terms and conditions for the following purposes of this chapter, namely:-

(a) Grant or renewal/retention of a license for the manufacture for sale or distribution, or sell or stock or exhibit or offer for sale, ordistribute of drugs or any specified drugs or class of drug or of cosmetics or any specified cosmetics or class of cosmetics.

(b) Inspection (for the purposes of grant or renewal of licenses) of premises, wherein any drug or cosmetic is being or is proposed to be manufactured or sold or distributed or exhibit or offered for sale or distribution;.

(c) Test or analysis of any drug or cosmetic by Government Analyst.

(d) Additional information required, if any, in the form of application for such licences, the conditions subject to which such licences may be issued.

(e) For electronic formats of forms, records, documents to be maintained by the licensee.

(f) Action on recall of not of standard quality drugs and cosmetics stocks.

(g) On such other matters as it appears to be necessary."

7. Amendment of section 33N.- In section 33N of the principal Act, after sub section (1), the following shall be inserted, namely:-

"(1A).The State Government may, by notification in the Official Gazette and subject to the condition of previous publication, make rules to prescribe the fees payable, wherever applicable, and of any other additional conditions for the following purposes of this chapter, namely.—

(a) Grant or renewal of a license for the manufacture for sale of Ayurvedic, Siddha or Unani drugs including *sow-rigpa* and homoeopathic medicines, and for sale of processed Ayurvedic, Siddha or Unani drugs including *sow-rigpa* and homoeopathic medicines.

(b) Inspection (for the purpose of grant or renewal of licenses) of premises, wherein any Ayurvedic, Siddha or Unanidrug is being or is proposed to be manufactured or sold.

(c) Test or analysis of Ayurvedic, Siddha or Unani drug by Government Analyst.

(d) For electronic formats of forms, records, documents to be maintained by the licensee.

(e) Action on recall of not of standard quality ASU drugs stocks.

(f) Any other matter on such other matters as it appears to be necessary to be prescribed under the relevant chapter.

8. Insertion of new section 39.- In the Principal Act, after section 38 the following new section shall be inserted, namely: -

"**39. Rules to be laid before State Legislature**.—Every rule made by State Government under this Act shall be laid, as soon as may be after it is made, before each House of the State Legislature, 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 afore said, both Houses agree in making any modification in the rule or both Houses agree that the rule should not be made, and notify such decision in the Official Gazette, the rule shall from the date of publication of such notification have effect only notification 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 or omitted to be done under that rule."

STATEMENT OF OBJECTS AND REASONS

It is considered necessary to amend the Drugs and Cosmetics Act, 1940 (Central Act 23 of 1940), in its application to the State of Karnataka to,-

(1) empower the State Government to specify such authority and such officer to carry out the functions of the Central Drugs Laboratory and the Director in respect of drugs or cosmetics in the State of Karnataka, with the prior approval of the Central Government;

(2) provide the burden of proof on the person from whose possession the drug or cosmetic was seized, that such drug or cosmetic is not misbranded or adulterated;

(3) prescribe life imprisonment punishment for subsequent Offences under section 30;

(4) prescribe all offences punishable under the Act to be cognizable and non-bailable;

(5) prescribe rules making power to the State Government under section 33 and 33N of the Act;

certain other consequential amendments are also made.

Hence the Bill.

FINANCIAL MEMORANDUM

There is no extra expenditure involved in the proposed legislative measure.

MEMORANDUM REGARDING DELEGATED LEGISLATION

Clause 6:	Sub-section (1A) of section 33 empowers the State Government to prescribe by rules the fees payable and of any other additional terms and conditions to fulfill the purposes under chapter IVA of the Act.
Clause 7:	Sub-section (1A) of section 33N empowers the State Government to prescribe by rules the fees payable and of any other additional terms and conditions to fulfill the purposes under chapter IVA of the Act.

The proposed delegation of legislative power is normal in character.

Dinesh Gundu Rao
Minister of Health and
Family Welfare Department

M.K. VISHALAKSHI
Secretary
Karnataka Legislative Assembly

ANNEXURE

THE EXTRACT OF THE DRUGS AND COSMETICS ACT, 1940
(CENTRAL ACT 23 OF 1940)

XXX XXX XXX

06. The Central Drugs Laboratory.- (1) The Central Government shall, as soon as may be, establish a Central Drugs Laboratory under the control of a Director to be appointed by the Central Government, to carry out the functions entrusted to it by this Act or any rules made under this Chapter :

Provided that, if the Central Government so prescribes, the functions of the Central Drugs Laboratory in respect of any drug or class of drugs or cosmetic or class of cosmetics shall be carried out at the Central Research Institute, Kasauli, or at any other prescribed Laboratory and the functions of the Director of the Central Drugs Laboratory in respect of such drug or class of drugs or such cosmetic or class of cosmetics] shall be exercised by the Director of that Institute or of that other Laboratory, as the case may be.

(2) The Central Government may, after consultation with the Board, make rules prescribing—

(a) the functions of the Central Drugs Laboratory ;

(d) the procedure for the submission to the said Laboratory under Chapter IV or Chapter IVA of samples of drugs or cosmetics for analysis or test, the forms of the Laboratory's reports thereon and the fees payable in respect of such reports;

(e) such other matters as may be necessary or expedient to enable the said Laboratory to carry

out its functions;

(f) the matters necessary to be prescribed for the purposes of the proviso to

sub-section (1).

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30. Penalty for subsequent offences.- 8[(1) Whoever having been convicted of an offence,-

(a) under clause (b) of section 27 is again convicted of an offence under that clause, shall be punishable with imprisonment for a term which shall not be less than seven years but which may extend to ten years and with fine which shall not be less than two lakh rupees:

Provided that the Court may, for any adequate and special reasons to be mentioned in the judgment, impose a sentence of imprisonment for a term of less than seven years and of fine of less than one lakh rupees;

(b) under clause (c) of section 27, is again convicted of an offence under that clause shall be punishable with imprisonment for a term which shall not be less than ten years but which may extend to imprisonment for life and with fine which shall not be less than three lakh rupees.

(c) under clause (d) of section 27, is again convicted of an offence under that clause shall be punishable with imprisonment for a term which shall not be less than two years but which may extend to four years or with fine which shall not be less than fifty thousand rupees or with both.

(1A) Whoever, having been convicted of an offence under section 27A is again convicted under that section, shall be punishable with imprisonment for a term which may extend to two years, or with fine which may extend to two thousand rupees, or with both.

(2) Whoever, having been convicted of an offence under section 29 is again convicted of an offence under the same section shall be punishable with imprisonment which may extend to two years, or with fine which shall not be less than ten thousand rupees or with both.

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32. Cognizance of offences.- (1) No prosecution under this Chapter shall be instituted except by

(a) an Inspector; or

(b) any gazetted officer of the Central Government or a State Government authorised in writing in this behalf by the Central Government or a State Government or by a general or special order made in this behalf by that Government; or

(c) the person aggrieved; or

(d) a recognised consumer association whether such person is a member of that association or not.

(2) Save as otherwise provided in this Act, no court inferior to that of a Court of Session shall try an offence punishable under this Chapter.

(3) Nothing contained in this Chapter shall be deemed to prevent any person from being prosecuted under any other law for any act or omission which constitutes an offence against this Chapter.

XXX XXX XXX

33. Power of Central Government to make rules.- (1) The Central Government may after consultation with, or on the recommendation of, the Board and after previous publication by notification in the Official Gazette, make rules for the purpose of giving effect to the provisions of this Chapter :

Provided that consultation with the Board may be dispensed with if the Central Government is of opinion that circumstances have arisen which render it necessary to make rules without such consultation, but in such a case the Board shall be consulted within six months of the making of the rules and the Central Government shall take into consideration any suggestions which the Board may make in relation to the amendment of the said rules.

(2) Without prejudice to the generality of the foregoing power, such rules may

(a) provide for the establishment of laboratories for testing and analysing drugs or cosmetics;

(b) prescribe the qualifications and duties of Government Analysts and the qualifications of Inspectors;

(c) prescribe the methods of test or analysis to be employed in determining whether a drug or cosmetic is of standard quality;

(d) prescribe, in respect of biological and organometallic compounds, the units or methods of standardisation;

(dd) prescribe under clause (d) of 5 section 17A the colour or colours which a drug may bear or contain for purposes of colouring;

(dda) prescribe under clause (d) of section 17E the colour or colours which a cosmetic may bear or contain for the purposes of colouring;

(e) prescribe the forms of licences for the manufacture for sale or for distribution], for the sale and for the distribution of drugs or any specified drug or class of drugs or of cosmetics or any specified cosmetic or class of cosmetics, the form of application for such licences, the conditions subject to which such licences may be issued, the authority empowered to issue the same the qualifications of such authority and the fees payable therefor and provide for the cancellation or suspension of such licences in any case where any provision of this Chapter or the rules made thereunder is contravened or any of the conditions subject to which they are issued is not complied with;

(ee) prescribe the records, registers or other documents to be kept and maintained under section 18B;

(eea) prescribe the fees for the inspection (for the purposes of grant or renewal of licences) of premises, wherein any drug or cosmetic is being or is proposed to be manufactured;

(eeb) prescribe the manner in which copies are to be certified under sub-section (2A) of section 22;

(f) specify the diseases or ailments which a drug may not purport or claim 10 to prevent cure or mitigate and such other effects which a drug may not purport or claim to have;

(g) prescribe the conditions subject to which small quantities of drugs may be manufactured for the purpose of examination, test or analysis;

(h) require the date of manufacture and the date of expiry of potency to be clearly and truly stated on the lable or container of any specified drug or class of drugs, and prohibit the sale stocking or exhibition for sale, or distribution of the said drug or class of drugs after the expiry of a specified period from the date of manufacture or after the expiry of the date of potency;

(i) prescribe the conditions to be observed in the packing in bottles, packages and other containers of drugs or cosmetics, including the use of packing material which comes into direct contact with with the drugs and prohibit the sale, stocking or exhibition for sale, or distribution of drugsor cosmetics, packed in contravention of such conditions;

(j) regulate the mode of labelling packed drugs 1[or cosmetics], and prescribe the matters which shall or shall not be included in such labels;

(k) prescribe the maximum proportion of any poisonous substance which may be added to or contained in any drug, prohibit the manufacture, sale or stocking or exhibition for sale, or distribution of any drug in which that proportion is exceeded, and specify substances which shall be deemed to be poisonous for the purposes of this Chapter and the rules made thereunder;

(l) require that the accepted scientific name of any specified drug shall be displayed in the prescribed manner on the lable or wrapper of any patent or proprietary medicine containing such drug;

(m) [XXX]

(n) prescribe the powers and duties of Inspectors and the qualifications of the authority to which such Inspectors shall be subordinate and specify the drugs or classes of drugs of cosmetics or classes of cosmetics in relation to which and the conditions, limitations or restrictions subject to which, such powers and duties may be exercised or performed;

(o) prescribe the forms of report to be given by Government Analysts, and the manner of application for test or analysis under section 26 and the fees payable therefor;

(p) specify the offences against this Chapter or any rule made thereunder in relation to which an an order of confiscation may be made under section 31;

(q) provide for the exemption conditionally or otherwise, from all or any of the provisions of this Chapter or the rules made thereunder, of any specified drug or class of drugs 1[or cosmetic or class of cosmetics and;

(r) sum which may be specified by the Central Government under section 32B.

XXX XXX XXX

33N. Power of Central Government to make rules.- (1) The Central Government may, after consultation with, or on the recommendation of, the Board and after previous publication by notification in the Official Gazette, make rules for the purpose of giving effect to the provisions of this Chapter:

Provided that consultation with the Board may be dispensed with if the Central Government is of opinion that circumstances have arisen which render it necessary to make rules without such consultation, but in such a case, the Board shall be consulted within six months of the making of the rules and the Central Government shall take into consideration any suggestions which the Board may make in relation to the amendment of the said rules.

(2) Without prejudice to the generality of the foregoing power, such rules may —

(a) provide for the establishment of laboratories for testing and analysing Ayurvedic, Siddha or Unani drugs

(b) prescribe the qualifications and duties of Government Analysts and the qualifications of Inspectors;

(c) prescribe the methods of test or analysis to be employed in determining whether any Ayurvedic, Siddha or Unani drug is labelled with the true list of the ingredients which it is purported to contain:

(d) specify any substance as a poisonous substance;

(e) prescribe the forms of licences for the manufacture for sale of Ayurvedic, Siddha or Unani drugs and for sale of processed Ayurvedic, Siddha or Unani drugs, the form of application for such licences, the conditions subject to which such licences may be issued, the authority empowered to issue the same and the fees payable therefor; and provide for the cancellation or suspension of such licences in any case where any provision of this Chapter or rules made thereunder is contravened or any of the conditions subject to which they are issued is not complied with;

(f) prescribe the conditions to be observed in the packing of Ayurvedic, Siddha and Unani drugs including the use of packing material which comes into direct

contact with the drugs, regulate the mode of labelling packed drugs and prescribe the matters which shall or shall not be included in such labels;

(g) prescribe the conditions subject to which small quantities of Ayurvedic, Siddha or Unani drugs may be manufactured for the purpose of examination, test or analysis; and

(gg) prescribe under clause (d) of section 33EE the colour or colours which an Ayurvedic, Siddha or Unani drug may bear or contain for purposes of colouring;

(gga) prescribe the standards for Ayurvedic, Siddha or Unani drugs under section 33EB;

(ggb) prescribe the records, registers or the documents to be kept and maintained under section 33KB; and

(h) any other matter which is to be or may be prescribed under this Chapter.

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