



CHALLENGES OF COSMETICS REGULATION

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INTRODUCTION

Drugs Control Dept is concerned with quality, safety, efficacy of the Drugs and Cosmetics.

One of the Responsibilities:

**To enforce Drugs & Cosmetics Act, 1940 and Rules
1945**

INTRODUCTION

- D&C Act, 1940 & Rules aimed at Self Compliance.
- Self Compliance is overseen by Drugs Control Authority by inspections.
- Exhaustive Rules stipulated in the form of Do's and Don'ts to achieve the objectives.

Definitions

- Section 3(*aaa*) -“cosmetic” means any article intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applied to, the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and includes any article intended for use as a component of cosmetic .

Definition

- The definition does not cover the cosmetics products meant for Vet. and /or Pet products . Therefore manufacturing license under the provisions of D&C Act , 1940 and Rules is not required.

Number of cosmetics products are available in the market meant for Pets.

If the definition is not amended the quality of Pet products can not be assured.

Definition

- **17C. Misbranded cosmetics.**—For the purposes of this Chapter, a cosmetic shall be deemed to be misbranded, --
 - (a) if it contains a colour which is not prescribed; or
 - (b) if it is not labelled in the prescribed manner; or
 - (c) if the label or container or anything accompanying the cosmetic bears any statement which is false or misleading in any particular.

- **17D. Spurious cosmetics.**—For the purposes of this Chapter, a cosmetic shall be deemed to be spurious,--
 - (a) if it is manufactured under a name which belongs to another cosmetic; or
 - (b) if it is an imitation of, or a substitute for, another cosmetic or resembles another cosmetic in a manner likely to deceive or bears upon it or upon its label or container the name of another cosmetic unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other cosmetic; or (c) if the label or container bears the name of an individual or a company purporting to be the manufacturer of the cosmetic which individual or company is fictitious or does not exist; or
 - (d) if it purports to be the product of a manufacturer of whom it is not truly a product.

Definition

- 17E. For the purposes of this Chapter, a cosmetic shall be deemed to be adulterated,—
 - (a) if it consists in whole or in part, of any filthy, putrid or decomposed substance; or
 - (b) if it has been prepared, packed or stored under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health; or
 - (c) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or
 - (d) if it bears or contains, for purposes of colouring only, a colour other than one which is prescribed; or
 - (e) if it contains any harmful or toxic substance which may render it injurious to health; or
 - (f) if any substance has been mixed therewith so as to reduce its quality or strength.”

Prohibition of Manufacture

- **18. Prohibition of manufacture and sale of certain cosmetics.**—From such date as may be fixed by the State Government by notification in the Official Gazette in this behalf, no person shall himself or by any other person on his behalf—
- (a) manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale or distribute—
 - (ii) any cosmetic which is not of a standard quality or is misbranded or spurious;
 - (v) any cosmetic containing any ingredient which may render it unsafe or harmful for use under the directions indicated or recommended;
 - (vi) any cosmetic in contravention of any of the provisions of this Chapter or any rule made thereunder;
- (b) sell, or stock or exhibit or offer for sale, or distribute any cosmetic which has been imported or manufactured in contravention of any of the provisions of this Act or any rule made thereunder;
- (c) manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale, or distribute any cosmetic ,except under, and in accordance with the conditions of, a licence issued for such purpose under this Chapter;

Entitlement of analysis report

- **26. Purchaser of cosmetic enabled to obtain test or analysis.**—Any person or any recognised consumer association, whether such person is a member of that association or not, shall, on application in the prescribed manner and on payment of the prescribed fee, be entitled to submit for test or analysis to a Government Analyst any cosmetic purchased by him or it and to receive a report of such test or analysis signed by the Government Analyst.

Explanation.—For the purposes of this section and section 32, “recognised consumer association” means a voluntary consumer association registered under the Companies Act, 1956 (1 of 1956) or any other law for the time being in force.

Difficulty in investigation

- License is not required for sale of Cosmetics.
- Cosmetics is being sold in grocery /petty shops. Hence it becomes opening to push Spurious/ adulterated Cosmetics.
- In absence of sales license, it is difficult to establish the link between the dealer and the manufacturer.

Standards

- As per Schedule “S” of D&C Act, standards for only 29 Cosmetics have been prescribed as per BIS Specifications. Standards for hair conditioners, body bath, shower gel etc are not prescribed. If standards for these Cosmetics are not prescribed, then these Cosmetics can not be declared as Not of Standard Quality.

Test Report in Form 34

- Govt. Analyst is required to issue Test report in Form 34 for Cosmetics. The said form 34 is required to be ammended to include protocols of the tests applied.

Stop production Orders.

- Licensing authority has powers to issue Stop production order to the manufacturer in case violations are detected in case of manufacture of drugs under Rule 85 of the Drugs and Cosmetics Rules. Such type of provision is not prescribed in case of Cosmetics in Rule 143.

Prohibition of certain colours

- **144.** *Prohibition of manufacture of cosmetics containing colours other than those prescribed.*- No Cosmetic shall be manufactured which contains Dyes, Colours and Pigments other than the one specified by the Bureau of Indian Standards (IS: 4707 Part I as amended) and Schedule Q.
- The permitted Synthetic Organic colours and Natural Organic colours used in the Cosmetic shall not contain more than–
- (i) 2 parts per million of arsenic calculated as arsenic trioxide.
- (ii) 20 parts per million of lead calculated as lead.
- (iii) 100 parts per million of heavy metals other than lead calculated as the total of the respective metals.

Prohibition of certain colours

- **144A.** *Prohibition of manufacture of cosmetics containing Hexachlorophene.*—No cosmetic containing Hexachlorophene shall be manufactured:

Provided that in the case of soaps Hexachlorophene may be used in concentrations not exceeding one per cent weight by weight:

Provided further that the following cautionary note shall be printed and shall appear in a conspicuous manner on the wrapper of package of each soap, namely:-

“Contains Hexachlorophene – not to be used on babies”

- **145.** *Use of Lead and Arsenic compounds for the purpose of colouring cosmetics prohibited.*—The use of Lead and Arsenic compounds for the purpose of colouring cosmetics is prohibited.

Penalty

- **27A - Penalty for manufacture, sale, etc., of cosmetics in contravention of this Chapter.** – Whoever himself or by any other person on his behalf manufactures for sale or for distribution, or sells, or stocks or exhibits or offers for sale –
- (i) any cosmetic deemed to be spurious under section 17D or adulterated under section 17E shall be punishable with imprisonment for a term which may extend to **three years** and with fine which shall **not be less than fifty thousand rupees or three times** the value of the cosmetics confiscated, **whichever is more**;
- (ii) any cosmetic other than a cosmetic referred to in clause (i) in contravention of any provisions of this Chapter or any rule made thereunder shall be punishable with imprisonment for a term which may extend to **one year or with fine** which may extend to **twenty thousand rupees**, or with both.



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Any Questions

