

Summary of roundtable on
“End to End Analysis of Drugs and
Magic Remedies(Objectionable
Advertisements)Act 1954
“Organised by Arogya Bharati and
Innovative Thought Forum

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CONTEXT AND BACKGROUND

It is very well known that manufacture, sale and distribution of drugs of all kinds came under radar of British government in India resulting into formation of drug enquiry committee(DEC) in the year 1930 with Col (Dr)R N Chopra as it's chairman. Chopra committee report is considered as the starting point of several legislations in the field of pharmaceuticals and drugs such as Drugs and Cosmetics act 1940.

Drugs and cosmetics rules 1945 , Indian pharmacy act 1948 etc .Due to inspiration from similar legislations in U K ,USA etc and preference of ruling elite and policy makers for modern /western/allopathic system , all the laws gave predominant place to it in public and private health .

Interestingly ,Dr R N Chopra had deep interest in plant based drugs as evident from his founding RRL ,Jammu (Now known as CSIR-IIIM).

Before independence and after it there were widespread advertising of all types of allopathic and Indian systems of medicines with wild,false , misleading and irrational claims luring people to consume them with several harmful side effects .

Drugs and magic remedies (objectionable advertisements) act 1954 was introduced with primary aim to check self treatment and self medication for 54 diseases as specified in the schedule and other stated conditions .The act hence prohibited all types of public communication or advertisements for drugs meant for prevention , diagnostics , mitigation and treatment . This act indirectly urged all the people to go through registered medical practitioners (RMPs) for medical help for specified diseases and conditions,

The act came under severe criticism over time compelling Government to go for amendment in 2020 and come with a draft .In this version advertisement definition was expanded to include electronic and other media and surprisingly expand the list of diseases from 54 to 78 .The draft remained on paper for reasons unknown to people .

POINTS FOR DISCUSSION

Though existent since 1954 ,DMR act ,1954 is not much understood , discussed or applied by regulators except in cases of complaints by competitors in trade or consumers .

As health is generally a state subject , emphasis or importance to this act varies a lot from state to state .Following points were broadly required to be discussed .

1. Historical background
2. Assumptions and rationale for vital provisions
3. Meaning of important terms like drugs ,advertisements and diseases in schedule
4. Important realities for amendment in 2020
5. Important cases relating to DMR act
6. Consumer protection thru DMR Act ,1954
7. Approach of regulators
8. Approach of courts
9. Feasibility of amendments
10. Important elements of a new consumer /patient friendly act

IMPORTANT POINTS DISCUSSED

Dr Ashok Varshney Ji, Organising Secretary, Arogya Bharati informed the group to discuss this Act, its implementation, gaps, scope for suggestions for pragmatic restructuring the DMR Act (1954) if need be.

S W Deshpande, Retd Joint Commissioner, Food & Drugs Department, Maharashtra State set the stage by lucid overview of the DMR Act and its provisions with exceptions viz section 14 (clinics, hospitals, Doctor, Scientific articles, Advt exclusively for the eyes of qualified registered practitioners).

Central Govt has made certain exemptions in case like. contraceptives by notifications. Section 7 about provision for penalties which is not deterrent in today's context along with poor implementation. Offenses are cognizable. DI of CDSCO are not empowered to take any punitive actions, however, against the defaulters of DMR Act.

Most of experts opined that Chopra committee was deeply influenced by allopathy. Dr R N Chopra and others wanted to apply scientific principles of Allopathy to discover mechanism of working of natural substances. The acts resulting from the work of the Chopra committee report like Drugs Act - 1940, Drugs rules - 1945, Pharmacy act 1948 etc. were Allopathy centric. Same thinking and approach applied to DMR Act, 1954

Following important points emerged from the overall discussions

- 1 Act needs to be revamped in totality.
2. Definitions of the following need to be modified:
 - a) Advertisement (It should include electronic, prints and social media)
 - b) Drug (Instead of drug "Product" was suggested to be used)
 - c) Disease
3. It was also suggested that the Act should be harmonized with / merged with new Drugs and Cosmetics Act.
4. The definition of Drug used in other Acts / Regulations such as Drugs and Cosmetics Act, Drug Price Control Order is required to be harmonized.
5. There should be provision for heavy penalties for non – compliance, so that they act as deterrent. Media, Advertisers / Advertising Agencies should also be made responsible along with the non-complying parties.
6. Appendix /schedule needs to be reviewed as Ayurved is offering treatment for atleast 18 diseases out 54 listed there. This is also needed because AYUSH came into existence in 1962 only.
7. Food Act should also be looked at and penalties for objectionable advertisements are to be aligned.
8. Vernacular Newspapers should also be watched very carefully for objectionable advertisements as these are connected with rural population. There should be a provision for 'corrective advertisement' in case violation is established and the party is penalized.
9. ASCI should implement 'Dos and Don'ts' in this respect. There can be a provision for pre-vetting of advertisements.

10. Patients/consumers Awareness steps should also be introduced in the Act.
11. Mashelkar Committee Report should be looked at for suggestions for a comprehensive Drugs and Cosmetics Act incorporating DMR Act having specific references to AYUSH, OTC, dietary Products and products of Nature Origin.

Way forward

- 1 Complete overhaul and drafting a fresh act keeping in mind the following
 - current context
 - current advancements in communications and advertising
 - harmonisation with other acts relating to drugs ,cosmetics ,medical devices ,consumer protection etc
- 2 Flexibility of compulsory review and changes every 5 years to keep act relevant to times
- 3 Simplification of the act with lucid and unambiguous language for reducing litigation
- 4 Reduction of criminalisation of companies , hospitals , practitioners,media etc
- 5 Thrust on self regulation by advertisers
- 6 Deterrent penalties on violators
- 7 Equitable and fair treatment to all segments of industry and disciplines like AYUSH and Allopathy
- 8 Exploring integration of DMR act with new D&C or Drugs,cosmetics and medical devices act under preparation
- 9 Importance to practical implementation and administration of the act keeping in mind limited manpower and capabilities
- 10 Further discussions to fine tune the changes to make act simple ,sensible ,pragmatic and consumer oriented .

Rgds

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