

### **RATIONALE DRUG THERAPY: REASONS FOR FAILURE AND SUGGESTIONS FOR ITS IMPLEMENTATION**

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Amending Act 68 of 1882 which came in force on February 1, 1983 vide note No. X-11012/1/81 DMS and PFA dated January 25, 1983 was a step in right direction for improving the quality of drugs being imported into, manufactured, distributed and sold in our country(1). The Government of U.P. in first schedule of CrPC, 1973 made changes with provisions of life imprisonment and fine for adulterating any drugs or medical preparations (vide U.P. Act 47 of 1975, Section-4). The market is overflooded with therapeutically useless and harmful preparations. Products such as—analgin, butazolidines, locally acting

antidiarrheals, clioquinols, cough syrups, tonics, liver protectives, enzymes, hyperosmolar electrolyte powders, hemoglobin preparations, anabolic steroids, tetracycline (Doxycycline) drops, antiperistaltic anti-diarrheals, brain tonics, baby tonics, gripe-water, pudin hara, arka pudina, bal jeevan ghutti, etc., account for more than 90% of the retail sale of drugs(2).

If a brand of drug is banned (e.g., fixed dose combinations of estrogen and progestogen i.e., E.P. forte), other similar brands are brought in black market as substitute for these (viz., T.P. forte, E.C. forte). Many Ayurvedic preparations, for which clinical trials have not been conducted for therapeutic efficiency and safety especially for young children are being marketed with impunity. Many medicines for babies have high concentration of alcohol e.g., arka pudina (79%), pudina hara (70%) etc. Alcohol may cause fatal hypoglycemia. The recent death toll caused by such preparations in several parts of the country are eye openers. "The Drug and Cosmetic Act 1940" has provision for preventing import, manufacture, distribution and sale of spurious, misbranded and adulterated drugs, but it is not effectively implemented.

1. Drugs of modern system of medicines are defined in law separately from Ayurvedic, Siddha or Unani medicines. Therefore, manufacturers take advantage of this lacuna by making spurious/harmful drugs branded as those of Ayurvedic, Siddha or Unani systems of medicine. Ginseng-roots which have been used alongwith vitamins and minerals in several preparations (Revital, Biovital

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30-plus, etc.) are very expensive and are of little proven benefit. Their import is a severe drain on our foreign exchange reserves. Alcohol, camphor, oral sodium bicarbonate and salicylic acid which have no scientific basis in therapeutics are routinely used in Ayurvedic medicines

2. Definition of "Drug" includes minerals, vitamins, brain tonics, appetizers and enzymes; manufacturers make combination preparations of these with subtherapeutic individual drug dosage and they cost 60% of total patient's expenses.

3. The "Drugs Technical Advisory Board" consists of persons from drug laboratories, Medical Council of India, persons from drug industries, Pharmacy Council of India and other nominated persons by Central Government. The Director-General of Health Services acts as Chairman. This board does not include any member, who practices medicine and who has expertise in rationale drug therapy. The industry has influence in deciding what to import, manufacture and sell in the country. There is no one from the consumers to decide and what is needed. It is obvious from the research report of Regional Drug Laboratories in India, that they are very much influenced by drug industries. Similarly, the Drugs Consultative Committee should include specialists from the field of medicine and pediatrics working for rationale drug therapy. Their recommendations should be based on facts and scientific evidences.

4. Facilities for testing, standard quality of a drug, misbranding and adulteration at district and state levels are

extremely limited (there are only five regional laboratories). The law without provisions to collect evidence can not be effectively implemented.

There are more than 12,000 formulations and millions of drug distributors and chemists in our country. One chief Drug Controller of India with five quality control laboratories and five hundred drug inspectors and an inadequate law can not affectively control drug menace(2).

5. The Drugs and Cosmetics Act 1940 mentions "No person who has any financial interest" shall be appointed to be an inspector. Since, there will be hardly any one who has no financial interest, the drug inspectors who are the back-bone of this Act, should not exist. Furthermore, 500 inspectors are far too less for a country like India. The same inspector is often responsible for implementing the Act for drugs, as well as cosmetics and drugs of other systems of medicines.

6. The preparation, uniformity of available dosage form of a particular drug is not assured by the present Drugs and Cosmetics Act. Isoniazid suspension is supplied by one pharmaceutical company as 100 mg/5ml and by another pharmaceutical company as 200 mg/ 5 ml. Similarly, there is no regulation in the manner of labelling, packing and dispensing measures. The law enjoins on the drug manufacturer to mention the drug content in each 5 ml or 1 ml. If transparent measures of 5 ml or 1 ml are not supplied in each package, it becomes a futile exercise.

7. Licensing authorities must be accountable. Over 95% of the medical stores have untrained, ill trained, less

educated or sometimes uneducated personnel. The local administration looking after the law and order has no authority to check this.

8. There is no definite system to regulate the cost of drugs. Even for useless preparations such as tonics; tonic "A" costs Rs. 15 per 200 ml; tonic "B" with same ingredients and same bottle costs Rs. 32 per 200 ml. Some manufacturers/formulators promote their preparations by unscrupulous methods of sharing their income with prescribers or through illegal incentives or gifts. Such practices raise the cost of drugs which is a burden on the patient.

9. The Drug and Cosmetics Act has no control over the prescriber to restrain him or her from irrationale prescriptions.

10. Some medical associations organize meetings, conferences, workshops and seminars through financial help from drug industries. Medical journals are subsidized by advertisements from the drug firms. This indirectly promotes irrationale therapy.

11. Some drug firms promote their products quoting unscientific, biased reports, published in their in-house journals.

Rationale drug therapy is the need of the hour(3-6). The "Drugs and Cosmetics Act 1940 and Rules, 1945" should be made effective through amendments in the light of the above observations.

A few suggestions are discussed as follows:

1. Essential drugs should be codified. Some essential drugs included in Schedule "X" such as phenobarbital and in Schedule "K" *e.g.*, primaquine

could be made available at least at one or two medical stores in all districts.

2. The drugs from other systems (Ayurvedic, Unani, Homeopathy) with sufficient proven scientific merit be included in these schedules.

3. Combination preparation of drugs from two or more systems of medicine should not be allowed.

4. There should be at least one inspector for 100 drug stores and at least one analytical laboratory in each state.

5. Clinics with sufficient interest and expertise in rationale drug therapy should be associated with the Drugs Technical Advisory Board and the Drugs Consultative Committee.

6. The licensing authority should comprise a panel of prescribers and administrators rather than a single inspector or drug controller.

7. The Ministries of Health should consider subsidizing medical conferences and journals to make them less dependent on drug houses. The Government may consider a levy on the drug firms for this purpose.

8. Code for manufacturing and marketing of baby food products should be enforced expeditiously.

9. The prescribers should be made accountable for prescribing irrationale/harmful medicines unnecessarily.

10. The code for sale promotion and price control should soon be enacted.

11. The registration of practitioners should be reviewed periodically. It should be mandatory for them to attend reorientation courses in concerned medical institutions every 3 to 5 years.

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