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# MEDICAL PRODUCTS AND LAW: The Indian Model

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In the American model we find law ensuring quality to prevent any fall in standards of quality, durability, reliability, safety, effectiveness and performance of the product. The appropriate standards are fixed by law. The manufacturer's performance in conformity with the law is monitored. To facilitate such inspection, documentation is mandatory for the identity and quality of raw material. The various stages of manufacture are also covered by records maintained by the manufacturer. This enables the inspecting staff to trace back the sub standard product through the earlier stages to the raw material which yielded it. This also enables the manufacturer to recall all products from the market should it be necessary to do so. All this is achieved by the statute, The Drug and Cosmetics Act and The Good Manufacturing Practices Regulation which is part of The Code of Federal regulations. (See separate note: Medical products &Law: The American Model)

In India, The Drug and Cosmetics Act, 1940 covers this field. s.3 defines "Drug" to include devices included for internal and external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals. The Act regulates the import, manufacture, distribution and sale of drugs and cosmetics. Under the Rule making power, elaborate rules have been framed, The Drugs and Cosmetics Rules 1945. The manufacture is to be done under a license which requires the licensee to provide qualified staff, maintain records of raw materials, manufacture and labelling. Inspection & sampling, testing & furnishing the protocols of the tests are the methods of control. Suspension or cancellation of license, withdrawal of sub-standard raw material or finished product are the methods for the enforcement of quality standards. The manufacturer may be prosecuted for not conforming to the statutory standards of production. Fine and/or imprisonment are the stipulated punishments. The manufacture and sale of sub-standard drugs and medical appliances are sought to be prevented by this Act.

What is missing is the emphasis on preventive steps, stage by stage to ensure conformity by the manufacturer to the stipulated standards. May be, it is a matter for implementation to achieve such a thrust.

The law in India regarding medical product liability is covered by The Law of Contracts, in general, and by The Sale of Goods Act in particular as well as The Law of Torts. The stipulations in the contract between the manufacturer and the buyer of the medical product govern the liability of the manufacturer. There are, of course the warranties. The purchaser is protected by The Sale of Goods Act, 1930 (s.16) in many ways. If the seller knows the purpose for which the purchaser buys the goods, the law presumes that the buyer relies on the skill and judgement of the seller that the goods are reasonably fit for the purpose for which they are bought. This is an exception to the rule of Caveat Emptor. Such an implied condition is not permissible where the buyer relies on a trade mark or patent in which he has confidence. Even if the purchaser has inspected before purchase, he is protected against any defect which is not discernable by a reasonable examination. There is no implied condition as regards defects which such examination ought to have revealed. "Exclusion clauses" will rule out such liability. A medical product may be used by the patient directly without the intervention of the doctor. As part of the treatment, a doctor may use a drug or an appliance on the patient. Tort Law imposes a duty of reasonable care and caution on the doctor in using the medical products and the patient or subject of research. Tortious liability would arise if and only

when the substandard drug or appliance becomes lethal in the sense being harmful to the patient. Medical ethics require a doctor to detect substandard quality of drug or appliance and avoid using it on the patient. Tort law enjoins on him an obligation to use reasonable care and caution in ensuring that he does not use substandard drug or appliance which is likely to cause damage to the patient. By holding himself out as a qualified professional, he is deemed to have represented tot he public in general, and his patient in particular, that he is reasonably competent enough to assess the tools he uses. If he defaults, it becomes part of medical negligence if the defect is patent. In addition to this, this assurance can be made part of the contract between the doctor and the patient. The intervention of the doctor does not alter the manufacturer's liability.

There are no elaborate or legally enforceable regulations in India assuring the quality and safety of medical products as we find in the U.S.A. and other countries.

The Industries (Development and Regulation) Act of 1951 and the rules framed thereunder, bring under central control the development and regulation of a number of industries affecting the country.

S.15 of the said act empowers the government to investigate any of the industries scheduled therein and issue directions under S.16 to take such steps as may be necessary for fixing standards of production . In the first schedule item.14 is entered as "Medical and Surgical Appliances" with a sub heading "Surgical instruments - Sterilisers, Incubators and the like". It is essentially a machinery for government control of the industry. The factor of product quality contributes to the standard.

Would this suffice for quality control ? Is the machinery erected under this act adequate to cover all aspects of product liability ? Does it touch on preventive control ? Is this quality assurance program laced in the manufacturing program, stage by stage ?

The fundamental concept of quality assurance is one of anticipatory action on quality problems. They have to be prevented from occurring. I.S.I.work in that direction. It is a statutory insistence and assurance of quality. But is it obligatory to seek and obtain this certification ?

The need:

What is needed is an active and total quality assurance system for protection of the public from harm. It should be mandatory under law. It should cover the product from design to raw material to finished product to labels and to actual use. Post-marketing activities should include complaints and investigation. It should be legally obligatory for the user to report any death, serious injury from the product or any improper use of the same. Law should require the result of the investigation to go back to the manufacturer, so that a recurrence may be avoided. A consistent product vigilance has to be ensured by law.

REFERENCES:

AMERICAN MODEL:


1. The Good Manufacturing Practices Regulation
   and The Good Manufacturing Practices Manual
   Published by The U.S.Food & Drug Administration under The U.S.Department of Health & Human Services.
2. The Code of Federal Regulations of U.S.A.
3. The Food, Drug & Cosmetics Act of U.S.A.
4. The Fair Packaging & Labelling Act of U.S.A.

5. The Radiation Control for Health & Safety Act of U.S.A.

INDIAN MODEL:

1. The Industries (Development and Regulation) Act 1951
2. The Law of Contracts
3. The Law of Torts
4. The Sale of Goods Act
5. The Industries (Development and Regulation) Act 1951
6. The Drugs And Cosmetics Act 1941
   Rules 1945
7. The Food Adulteration (Prevention of) Act 1954,
   Rules 1955
8. Drug Price Control Order.
9. The Poison Act
10. The Pharmacy Act