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Regulations on export and manufacture of drugs in India

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Exports form a vital component of the growth strategy of most Indian pharmaceutical companies. The industry has made rapid strides in this area in the last few years and export sales of companies such as Ranbaxy have been growing at a faster rate than their domestic sales. The compounded annual growth rate of pharmaceutical exports over the last five years has been more than 20 percent although in 2000-2001, exports grew by 11 percent. While overall pharmaceutical exports have grown, India's exports to a few of its leading markets have declined. For instance, India's pharmaceutical exports to USA have declined to Rs. 671.8 crores in 1999-2000 from Rs. 724 crores in 1998-99; Germany to Rs. 325 crores from Rs. 375 crores. Notwithstanding the decline in exports to some key markets, India's export prospects remain bright. The potential for growth is enormous, annual growth in exports over the next five years will take the overall export figure to \$4 billion.

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Research driven drug act: Need of the day

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The history of Drug Act of USA, which is thus far supposed to be the most stringent and successful in securing safe and effective medicine trade reveals that ever since its inception in 1906 till the 1962 amendments, every time, disaster prompted framing and amendment of the law. With advances in medical and pharmaceutical sciences, far ahead of time, and advanced data base analyses and management in place, this trend need to be revisited. Spectacular advances in research relating to drug metabolism and drug-drug interactions supported by precise data processing, has paved way for fast tracking of the consequences of complex therapeutic environment. This knowledge deserves to be home driven in reshaping Drug Act on a continuous basis. As like continuous improvement of pharmaceutical products, the laws governing all activities relating to manufacture and sale of medicines must improve continuously and be up to mark, in greater interest of health and happiness of people. In a life saving enterprise, there should be no room for waiting to learn from disasters, that too in the fast growing scientific era. The scientific fraternity should rather conceive, simulate and carry out research whose outcomes could accurately guide the framework of law on a continuous basis. Only such action in place shall assure total quality management of Drug Act. The regulatory authorities need a research and analysis wing Centre, which works in collaboration and co-operation with industry, research laboratories and academic. This joint effort should bring out the vision document for continuous improvement of drug laws across the world. The time is ripe to sow the seed for research driven Drug Act instead of disaster driven as it has been hitherto.

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