From Chairman's Desk

Discovery of novel therapeutic agents

The hide and seek between diseases and drugs make it sure that need of new drugs will continue for all times to come. Discovery of novel therapeutic agents is evergreen area and so are the prospects of pharmaceutical industry. Diseases never discriminate between rich and poor or elite and downtrodden, it afflicts every one with same severity. Nature's treasure is abundant. Scope for its medicinal application is also profuse. What is needed is dedicated scientific approach to translate phytochemicals into safe and effective medicine. It's high time to look back to nature and seek answer for every problem and medicine cannot be an exception.

Botanical therapeutics is new generation of plant-derived pharmaceuticals, nutraceuticals, functional foods and plant-produced recombinant proteins, useful for human health. These have huge market share across the globe. The traditional Indian medicines were derived from natural sources and majority of them from plant origin. They need to be evaluated on modern scientific lines to acquire the fame of evidence based medicines. This proposition is fundamental to establishing safety and efficacy of such products and their global acceptance. This will mean revival of traditional medicines and better business opportunities. This is no new hypothesis. It is an already tested method of US FDA as back as in 1966 when it contracted with the National Academy of Sciences/National Research Council to evaluate the **effectiveness of 4,000 drugs** approved on the basis of safety alone between 1938 and 1962. This was called **Drug Efficacy Study Implementation (DESI).** Following thalidomide tragedy the Federal Food, Drugs and cosmetics Act was amended by the Kefauver-Harris bill 1962 authorizing the FDA to test old as well as new drugs for efficacy. The FDA lacked the personnel to do these tests, so the National Academy of Sciences appointed a special committee to perform efficacy investigations in bulk. The Drug Efficacy Study Implementation (DESI) committee was composed of 160 physicians, who relied on their pharmacological knowledge, literature reviews, clinical experience, and intuition. By 1984, final action had been completed on 3,443 products; of which, 2,225(64.62%) were found to be effective, 1051(30.53%) were found **not to be effective**, and 167(4.85%) remained pending. This initiative weeded out almost 1/3rd of the products from market. Not only that but it also cemented the confidence of doctors and patients in the medicines available in US market. The initiative proved a project of highest social, business and welfare impact. It protected the society from substandard medicines. It helped industry to increase business of standard medicines. It helped patient in getting cured and reducing unnecessary medical expenses.

The scenario about all the traditional medicines which are not evaluated for safety and efficacy on modern lines may not be much different from the US experience. Extension research on evaluation of all such products in market is the compulsory need in greater public interest. This will ensure weeding out of irrational products, placebos and unsafe products from market and improve the business of evidence based traditional products in global market.

According to Global Industry Analysts, Inc., (GIA) Global Traditional medicine market will reach US$114 billion by 2015 because of accelerated Consumer interest in alternative medicine (AM) across the globe on account of rising healthcare costs of modern therapies. Chronic diseases like hypertension, depression, sleep disorders, and other lifestyle-related diseases, can be safely and economically treated by traditional medicines.

The diseases like arthritis and other degenerative disorders such as heart disease, diabetes, and cancer, headaches, and anxiety can have more safer and effective botanical therapeutics. Sales figures support that herbal medicines are most commonly used in flu, burns, and colds.

Once extension research projects are undertaken for critical evaluation of botanical therapeutics several risks associated with such remedies, like toxicity, unwanted side effects, injury to vital organs can be effectively addressed and redressed.

Another problem which will be solved by the proposed initiative is that restrictions and ban imposed on several botanical therapeutics due to lack of sufficient research and testing may be lifted and liberalized once the process of organised and monitored research publish its findings and successful products are *ipso facto* certified. Policy makers must realize the importance of this proposal and industry must come forward. This will definitely improve business.

Prof. Suresh Nagpal