

exist in their own right, transcending these tools.

Second, the study of earth sciences in India is at its lowest ebb. This is evidenced by dull, descriptive teaching of courses untouched by the excitement of modern science, lack of enrolment of students seeking earth science as their prime choice, research output lagging behind international levels and a distinct lack of presence of earth sciences community in major institutions. This assessment of earth sciences in India must be a matter of grave concern because India's economic prosperity and social well-being are at great risk if the country's earth resources (land, water, mineral resources and ecosystems) are not managed properly. Management of earth resources requires skills and techniques that are different from those of physical and biological sciences.

Third, whereas earth sciences is currently a melting pot of disciplines, India's own institutions are notably insular. This observation captures the sentiment expressed at the beginning, that earth knowledge is in a state of transition due to the evolution of that knowledge. The days of mutually insulated specialized disciplines have given way to collective, multi-disciplinary understanding of interconnected earth systems on various spatial and timescales. This need for collective effort is not motivated merely by intellectual curiosity. The civilized future of our technological society vitally depends on such a collective, broad-based approach.

Concluding remarks

Since independence, India's educational focus has slanted towards technology, commerce and more recently, law. This is evidenced by India's reputed institutes of technology, regional engineering colleges, business schools and national law schools of excellence. Compared to these, earth education has received lesser attention.

India is now at the onset of impressive economic growth. There is optimism that economic growth will pave the way for poverty reduction and improvement in the condition of all Indians. Yet, this optimism will come to nought if the country's water, land and ecological resources are not properly managed. The Indian subcontinent has experienced continuous human habitation for millennia. This, combined with India's population growth, has led to significant stresses on the natural resources base. Even to sustain the economy at the present levels and assure equitable distribution of water, India has to manage its water and land resources far better than what it does now. Growth beyond existing levels will inevitably demand additional quantities of water, construction materials and land. Management is the key to meeting these demands. Such management will require adequately funded, new institutional infrastructure and personnel trained in earth knowledge.

For a healthy economic future, India has to draw upon earth knowledge at a

level that is on par with physical sciences, business and law.

To mobilize earth knowledge, there has to be a concerted effort by the common citizen, teachers in elementary schools and the universities, various industries, the academies of science and the government to address issues of earth education. India is already facing a situation in which its academic institutions are unable to meet manpower demands in earth sciences and engineering. The short-term solution to this problem may be to attract, through adequate incentives, talented individuals from other fields, who would be willing to direct their skills to understand the earth. Considering the growing awareness around the world of a shrinking planet, inducing these individuals to take interest in the earth may indeed prove rewarding to all concerned.

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Fixed dose combinations: Rational or irrational?

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Fixed dose combinations (FDCs) are combinations of two or more drugs present in a dosage form. Rational drug therapy means the use of the right medicine in the right manner (dose, route, frequency of administration, duration of therapy, etc.) in the right patient at the right cost and at the right time. In an effort to initiate rational drug therapy, the World Health Organization (WHO) introduced the concept of an essential drugs list in 1977 and it updates the model list every two years¹.

Subsequently after two decades in India, the Delhi Society for Promotion of Rational Use of Drugs (DSPRUD) was formed to promote the rational use of drugs. The 15th list of essential medicines by WHO has only about 25 FDCs². However, it is staggering to find that over 80,000 formulations are sold in the Indian market, which include several FDCs and other single drug formulations.

Although various opinions have been expressed regarding the rationality of

FDCs, there are only a few studies taken up to find the rationality of FDCs. One such study carried out in M.L.N. Medical College, Allahabad, has elucidated the rationality of FDCs prescribed by doctors using the WHO list of essential medicine³.

There has been an alarming increase in irrational FDCs in the recent past and pharmaceutical companies manufacturing these FDCs are luring physicians to prescribe their products even when they

Table 1. Irrational combinations as listed by CIMS in 2006

FDCs	Irrationality	No. of brands available in CIMS, 2005
Nimesulide + paracetamol	Nimesulide is banned in most countries and combining two NSAIDs may increase the side effects of both. Also, there is no documentary evidence to support that combination is more effective than a single ingredient.	21
Enalapril + losartan	Two drugs affecting the same pathway do not add to efficacy.	3
Norfloracin + tinidazole	Combination of antiamebic with fluroquinolone is irrational as a patient suffers from only one type of diarrhoea. It may encourage resistance.	47
Atorvastatin + nicotonic acid	Probability of myopathy may increase.	4
Cetirizine + phenylpropanolamine + paracetamol	Phenylpropanolamine is banned because of its potential to cause stroke, glaucoma and prostate enlargement.	6
Amoxicillin + cloxacillin	Amoxicillin is inactive against staphylococcus and cloxacillin is not very active against streptococci. One of the components is useless for any given infection and the amount of each drug is halved, thus increasing the chances of resistance.	27

are not needed by the patients. This may be due to the implementation of product patent regime, where several pharmaceutical companies find various alternatives to sustain themselves in the marketplace and combination products for newer indications play a major role⁴. The irrational FDCs particularly have flourished and become highly popular due to ingenious marketing techniques of the pharmaceutical companies. Instead of investing money in research and development to develop new molecules, most companies create and manufacture so-called novel products by just mixing two or more drugs. The Current Index of Medical Specialties (CIMS) for the year 2006 lists more than 100 irrational combination brands⁵. Some of these are listed in the Table 1.

The Monthly Index of Medical Specialties, June 2007 has listed 136 irrational combinations⁶. Even though the list of irrational combinations is clearly mentioned in such indices, some physicians and unqualified medical practitioners prescribe these dubious FDCs to the patients. Responding to the allegations that irrational FDC tablets were being sold in many States, the Union Health Ministry has sought a report from the States on the availability of FDC tablets, which have not been approved by the Drug Control Section for their irrational combinations. Presently, 294 FDCs are pending for approval by the DCGI after the licenses were issued from State Drug

Controller. Out of the 294 FDCs, 78 FDCs are liable to get approval by the DCGI under certain conditions⁷.

For the consumer, the usage of these irrational FDCs can lead to increased adverse drug reactions, unnecessary hospitalization and financial burden. While for the prescriber it is difficult to individualize the dose and he/she could face problems when subjected to litigation in the consumer court, as these combinations find reference neither in standard textbooks nor acclaimed journals. Unfortunately, there seems to be no uniform worldwide acceptable criteria to define irrational FDCs and currently there are no uniform principles, guidelines or international standards addressing their development and regulatory assessment. Only a few countries have specific regulatory guidelines in place and so irrational combinations are still rampant in several markets.

Questions which may arise against the irrational combinations are as follows: Why do pharmaceutical companies indulge in manufacturing irrational combinations? Why do physicians prescribe irrational combinations and why do the regulatory authorities approve these irrational FDCs? There are more questions than answers regarding the irrational FDCs.

There should be an end to the blame game, where pharmaceutical companies, healthcare professionals and regulatory authorities blame each other regarding

the presence of FDCs in the marketplace. They should take the initiative and try to curb the menace of these irrational FDCs.

Pharmaceutical companies should not indulge in immoral practices by manufacturing these irrational combinations due to high competition. Also the pharmaceutical promotional practices must be trustworthy with high ethical standards. There should be justifiable scientific proof for the claims regarding the drugs that they market and information should be clear on all the aspects (indications, adverse effects, drug interactions and precautions) that will help physicians to prescribe the right drug to the right patient.

It is said that pharmaceutical promotion affects a physician's prescribing habits. However, it is inappropriate to be biased while prescribing a drug which may even affect the physician-patient relationship. As physicians are final decision makers as to which drug should be prescribed to the patients, they should never be influenced by the pharmaceutical companies' exaggerative statement. If a physician is not certain about the status of new combination available, he should delay his prescription until the efficacy and safety of the combination are well tested and approved by the respective regulatory authorities.

The amendment of Drugs and Cosmetics Act in 1982 gave the Government enough power to prohibit the manufacture and sale of FDCs and irrational drugs. Most of the combinations which are marketed

by companies are permitted by the State Drug Authorities, which is in clear violation of the law in the first place. The new combinations are termed 'new drugs' according to the Drugs and Cosmetics Act (Rule 122 (E)); they must, therefore, undergo clinical trials and safety studies to qualify for entering the market⁸. Since specific guidelines do not exist, regulators need to establish clear quality, safety and efficacy standards for registration of new FDCs and should critically review the existing FDCs in the market. The pharmaceutical companies should not be allowed to take advantage of the absence of specific regulatory requirements needed for registering FDCs. The pharmaceutical industry should not be allowed to self-regulate with respect to promotion of a

new drug, as misleading or inaccurate information may have serious implications. It is high time that pharmaceutical companies, healthcare professionals and regulatory authorities join hands and prescribe guidelines for the manufacture and sale of FDCs.

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