tion. Approximately one third of all CO_2 emissions due to human activity come from fossil fuels used for generating electricity, with each power plant capable of emitting several million tonnes of CO_2 annually. A variety of other industrial processes, for example oil refineries, cement works and iron and steel production also emit large amounts of CO_2 from each plant. These emissions could be reduced substantially, without major changes to the basic structures, by capturing and storing the CO_2.

Injecting CO_2 into methane-rich coal seams hundreds or thousands of feet underground could have a double benefit of boosting energy production and at the same time reducing greenhouse gas emissions. Many unmineable coal seams have associated methane that is adsorbed on the coal. Field tests carried out in North America have shown that CO_2 pumped down an injection well into a deep, unmineable coal seam may be adsorbed on the coal bed, displacing the methane and forcing it to rise up through a production well. Carbon sequestration in selected Gondwana coalfields of India may provide valuable leads regarding application of CO_2 for enhanced CBM recovery and at the same time provide a viable avenue for long-term sequestration of CO_2.

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Combination drugs: Are they rational?

Combination products also known as fixed-dose combinations (FDCs) are combination of two or more active drugs present in a dosage form. The Food and Drug Administration, USA defines a combination product as a product composed of any combination of a drug and a device or a biological product and a device or a drug and a biological product or a drug, device, and a biological product[1].

Several branded formulations are available in India which are either single or fixed dose combination drugs. No doubt all the formulations are meant for prevention or treatment of ailments and diseases, out of which only a few drugs are lifesaving and essential; rest of the drugs are substitutes for each other. The safety of the combination drugs has to be thoroughly evaluated and there are considerations for the drugs that are already in the market as individual or single drug entity. However, the safety profile of the established drugs will alter when they are combined together. There was alarming increase in irrational FDCs in recent years and pharmaceutical companies manufacturing these FDCs are luring physicians to prescribe by unethical means. This may be due to the implementation of product patent regime where the mediocre companies find various alternatives to sustain themselves in the market place and combination products for newer indications play a major role. The total number of essential drugs mentioned in the 14th list of essential medicines by WHO is 312, out of which only 18 are fixed dose combinations[2]. But many of the irrational combinations are popular and widely prescribed by physicians in our country. The combinations such as tetracycline and vitamin C, quinolones and nitroimidazoles and penicillins with sulfonamides are some of the examples of irrational FDCs. Such dubious FDCs entail financial burden, resistant strains of bacteria and increase in unwanted effects. The regulatory requirements for approval of combination products vary from country to country and there are no specific regulations in our country.

In our country, after amendment of the Drugs Act in 1982, the Government has acquired the power to prohibit manufacture and sale of certain drugs and irrational FDCs. The government, subsequently, issued a first gazette notification in July 1983 banning several drugs and their FDCs after due consideration. Since then the government has been notifying the list of banned drugs on a regular basis[3]. The Drugs Controller General of India (DCGI) had issued an order in May 2002 to State drug-controlling authorities not to grant any manufacturing or marketing approvals for new drugs. Since then DCGI has become the centralized authority for granting new drug approvals. This has affected many companies who have already established manufacturing units for their approved FDCs by the State drug-regulatory authorities.

The principal regulatory body, USFDA is not convinced of the rationality behind combination products other than anti-tubercular and anti-AIDS drugs. Due to continuous demands from pharmaceutical companies, they had established the office of combination products in 2002 and they had approved a few combinations in anti-diabetic and cardiovascular segments. Regrettably there are no guidelines for the combination products with specific demarcation of chemical, herbal, biological products and devices. As of now, there is only a guidance draft available at office of combination products, USFDA website. Hence, there exists confusion in manufacturing and rationality of the FDCs.

As the wellbeing of a patient's health lies in the hands of healthcare professionals and pharmacists, it is essential for them to get acquainted with the list of drugs which are irrational and banned by DCGI. In addition, they should keep themselves updated with the notifications issued by the DCGI to curb irrational fixed dose combinations. Moreover, regulatory authorities, healthcare professionals, researchers and pharmaceutical companies should join hands together to formulate guidelines for the FDC's to drive away fear from the minds of patients.

1. Office of Combination Products, Food and Drug Administration, USA: www.fda.gov/oc/combination/21 CFR Part 3.2(e).
2. http://whqlibdoc.who.int/hq/2005/a87017_eng.pdf
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