Health Economic and Outcomes Research and Market Access of Medicines in India – Current Perspectives

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Health economic and outcomes research (HEOR) activities consists of Pharmacoeconomics (PE) research and Health Technology Assessment (HTA) activities. The HEOR activities monitor and evaluate health care services including therapies and interventions. HEOR provides effectiveness, evidence-based justifications, and economic value of the health care interventions and therapies (medicine/drugs and medical procedures).

India is the third largest producer of drugs by volume and Indian pharmaceutical industry has a diversity of generic medicines. Public sector (government) allocates only 22% of the total expenditure on health. About 80% of health care spending is out of pocket (OOP) and paid by citizens, and 75% of OOP is spent on drugs and medicines and is many times a reason for financial crisis in families [1-4]. The existing formulary system is very weak, standard treatment guidelines (STGs) only exist on paper and are rarely followed, and the majority of the prescriptions are branded generics [1]. In addition, doctors are often bombarded with many new drugs of the same category along with existing drugs. Therefore, without any practicing guidelines of HEOR data, the introduction of new drugs can confuse the doctors and administrators’ judicious selection and rational use of medicines. Pharmacies largely sell branded formulations, which accounts for more than 95% of all drugs sold. There are more than 100,000 generic brands in the country, and doctors often prescribe a huge variety of generic brands for the same ailment / disease / health condition. Brand substitution is disallowed, hence, pharmacies usually dispense the prescribed branded generic (also there is another reason described in next paragraph), and this creates an additional challenge and strain to the pharmacies to stock all brands [5].

India does not have the bioavailability/bioequivalency (BA/BE) requirement for the approval process for available drugs. The dissolution test is not mandatory for most of drug formulations, and there is no requirement to prove whether a formulation will release an equivalent/comparable amount of drug into the blood stream with respect to the original brand or formulation. As a result, it is not known if a particular approved formulation (particularly with low solubility and absorption rates) will be effective and will release the specified and required amount into the blood stream. This could be a valid reason for no brand substitution, but still, there is no evidence that the doctor-prescribed brand will have BA/BE. The BA/BE is an established practice in developed countries, and a drug/formulation (branded or generic) needs to prove BA/BE before it gets approval for marketing. The BA/BE provides confidence and allows generic substitution. Although, there is a bio-waver for BA/BE for certain drugs that have high solubility and have high absorption rates [5].

The National Pharmaceutical Pricing Authority (NPPA) of India is responsible for drug formulations, bringing National List of Essential Medicines (NLEM), setting the drug prices through the Drug Price Control Order (DPCO) - the latest one is DPCO 2013, enforcing prices and availability of 348 NLEM drugs and over 600 formulations in India [www.nppaindia.nic.in]. The details of DPCO 2013 are discussed as another topic on pg. 8. Another government agency involved in drug approval and regulation is the Central Drugs Standard Control Organization (CDSCO). The CDSCO is a federal government authority for discharging functions assigned to the Government of India under the Drugs and Cosmetics Act of 1940 and the Drugs and Cosmetics Act (Amendment) of 2008. In terms of regulations and approvals, the CDSCO in India is similar to the Food and Drug Administration (FDA) in the United States. CDSCO’s mission is to safeguard and enhance public health by assuring the safety, efficacy and quality of drugs, cosmetics and medical devices [www.cdsco.nic.in] [1-2]. Similar to the Food and Drug Administration (FDA) in United States, the CDSCO in India does not require an economic analysis for Drug approval [1].

The HEOR activities in India are at an infancy stage and are also very fragmented - parts of activity are handled by different public agencies and private entities, such government ministries, departments, autonomous but publicly-funded agencies, and private insurers, and private health care providers. HTA and PE principles are vital parts of good prescribing practices, developing STGs, and rational use of medicines. The lack of good quality PE studies and guidelines is major hurdle in use of PE principles for prescribing in India, so the affordability, cost minimizations along with raw assessments are assumed in prescriptions and regulations, such as, NLEM, DPCO, and approval process through CDSCO [1-2, 6]. Since 75% of medicine cost is OOP in India, people need to know not only the effectiveness and efficacy but the value of the approved medicines. It is therefore the need of the hour
to establish a single umbrella organization in India to initiate HEOR activities, to develop STGs for health care providers, to establish BA/BE requirement in approval process, make BA/BE available for all drugs on websites similar to drug prices, and to allow generic substitutions for drug approvals, drug regulations, and market access of medicines.

Recently, there have been some initiatives toward HEOR activities in India. The Government of India is collaborating with NICE (UK) toward establishing HTA infrastructure in the country [7]. The National Health Systems Resource Centre (NHSRC), Amrita Institute of Medical Sciences and Research Centre, and IIT Chennai have jointly organized HTA training workshops, and a dedicated unit in the NHSRC is working on HTA. The Medical Technology Assessment Board has been established as a division of the Indian Council of Medical Research by the Government of India [8]. ISPOR India Chapter and HealthNetIndia are working to develop PE guidelines for India [9]. These HEOR activities and initiatives, though modest, will lead to provide an evidence-based support to all concerned agencies and people to evaluate the quality and value of available health care interventions (drugs, formulations, therapies, and health care technologies) and in the establishing of STGs for health care services.

References:
7. NICE to support development of HTA in India (June 21, 2013) www.pmlive.com/pharma_news

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The Drug Price Control Order (DPCO - 2013) of India

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Drug Price Control Order (DPCO) is the Government of India’s latest regulation to control the prices of available drugs in India [1]. The DPCO is formulated by National Pharmaceutical Pricing Authority (NPPA) which is a part of the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India. The NPPA is responsible for drug (medicine) formulations, bringing National List of Essential Medicines (NLEM), setting the drug prices through the Drug Price Control Order (DPCO), and also maintains the searchable database for the drug (by generic name) prices, and databank for all manufacturers, marketing, distributors of pharmaceuticals on its website. It is also constantly updated to include latest approved available drugs and their ceiling prices [2]. People can also register grievances of non-availability of drugs, overpricing of drugs, sale of non-approved drug, or refusal of sale of any medicine (drug). NPPA is also responsible for recovering overcharged amount, if any, by drug manufacturers from consumers for the controlled drugs [www.nppaindia.nic.in].

The latest DPCO 2013 enforces the prices and availability of 348 NLEM drugs and over 600 formulations. DPCO 2013 provides a formula to calculate the ceiling price of a scheduled formulations / drugs using a market-based pricing (MBP) method, taking into account the prices of all manufacturers having a national market share of more than 1% [1, 3]. The ceiling price of a drug is the maximum price a pharmacy can charge for the drug to a patient/customer. The formula to calculate the Average Price to Pharmacy Retailer P(PR) is – P(PR)= (Sum of prices to retailer of all the brands and generic versions of the medicine having market share more than or equal to 1% of the total market turnover on the basis of moving annual turnover of that medicine) / (Total number of such brands and generic versions of the medicine having market share more than or equal to 1% of total market turnover on the basis of moving annual turnover for that medicine). The formula for calculating the ceiling price of the P(C) would be: P(C) = P(PR) X (1+M/100), where the P(PR) = Average Price to Retailer for the same strength and dosage of the
medicine as calculated; M = % margin to retailer/pharmacy, the current value is of M = 16 [1]

Under this formula prices may fluctuate for the NLEM drugs and for approved formulations. Drug Price Control Order of 2013 has been criticized extensively for being myopic in its approach, as the number of formulations included is less than 20% of the whole pharmaceutical market [3-4]. The DPCO-2013 have many loopholes that pharmaceutical companies can exploit by changing marketing strategies for formulations and dosages not covered under the DPCO, such as the fixed-dose combinations. The result is evident that more than 90% of the anti-diabetic formulations are out of the purview of the DPCO. By this price control mechanism, ultimately the patients were at a loss because either important medicines were not available, or available in unnecessary combined formulations and at increased prices [5]. In the DPCO-2013 many of the Essential Medicines are included in price control, and many drug manufacturers reacted by stopping the production of some of those very important medicines, and by making changes in the formulations to escape price control. India needs a better cost effective price control mechanism to protect patients and consumers, where the share of drugs in out-of-pocket expenditure (OPP) is around 80%, against unnecessary formulations and exploitations. Policy makers should develop a tighter regulatory framework to provide better and cost effective medicines [3, 6].

References:

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