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Commentary

Generic drugs for public health in India: …….. Advantage India

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Abstract:
India has enormous distinguished advantages in the field of pharmaceuticals particularly in the production and distribution of quality generic drugs at affordable prices to the world. At home, various stakeholders like pharmaceutical industry, various governmental agencies, as well as doctors are doing their bits to ensure availability of quality medicines at affordable prices to all.

Commentary:
With more than a 1.2 billion population, more than a trillion US$ economy and 7.5% of expected economic growth in the fiscal year 2015-16; India ranks 2nd in population size, 4th in overall size of the economy and 1st in expected growth of any major economy in the world. In the year 2009, our total expenditure on health was 4.2% of GDP in which 30% was public health spending[1]. According to the Federation of Indian Chambers of Commerce and Industry (FICCI), India is world's 3rd largest pharmaceutical manufacturer by volume and 14th in terms of value. India is already the world's largest producer of generic drugs (GD), as more than 1/5th of world's generics are manufactured by IP companies[2]. India is not only the largest supplier of these affordable drugs to the third world and other developing countries but more than 200 countries import GDs manufactured by these IP companies. Indeed, India produces nearly 40% of GDs and over-the-counter (OTC) drugs and accounts for 10% of finished dosages in the US[3].

Though, there is no doubt about efficacy and safety of generic drugs (GDs) over branded drugs (BDs), a caution is still alarmed for some drugs with a "critical dose" or "narrow therapeutic index". At present bioequivalence of generics is only a problem of some 40 medicines like warfarin, digoxin, carbamezipine, phenytoin etc[4]. But, on the contrary, GDs are usually much safer than newly launched PDs, as a drug molecule is invariably present in the market for many years (with plenty of evidences on safety and efficacy of the drug) before its generic version is approved for manufacturing[5].

The debate of GD versus BD is not actually about efficacy, safety or convenience but this whole issue revolves around affordability and health rights of the poor versus cost of innovation and intellectual property rights of an originator. In India, where per capita income is only Rs. 74,104 (or ~US$1150) per year, 363 million (29.5%) people still live below poverty line (earns less than 47 Rs or 75 cents per day in an urban area and 32 Rs or 50 cents per day in a rural area)[6], spending on health care is the 2nd most leading cause of rural indebtedness after dowry[7], 70% expenditure on health is from out-of-pocket (OOP) resources, 43% people need to borrow or sell their assets to pay their hospital bills, 85% of people has no health insurance coverage[8], and almost all of the health insurance companies do not seem to cover medicine expenses at present[9], the situation is very grim. On the other hand, those who support BDs (mainly PDs) raise the issues of increasing cost of innovation (as of $2.6 billion per useable molecule in the year 2013), violation of intellectual property rights of an originator, reduced incentives for innovation and poor or unreliable quality of GDs in their support[10]. The research-based pharmaceutical industry is estimated to have spent nearly USD 137 billion globally on pharmaceutical R&D in 2012; which is 5 times greater than that of the aerospace and defence industries, 4.5 times more than that of the chemicals industry, and 2.5 times more than that of the software and computer services industry[11].

The Indian pharmaceutical (IP) market is estimated to worth around $31.9 billion a year in FY 2013, including exports ($15.6 billion)[12]. According to various sources, IP industry has somewhere between 10-24,000 manufacturing units, 4-5,000 marketing companies and employs nearly 3 million people, directly and indirectly[13,14,15]. Median consumer price ratio of medicines is amongst the lowest in the world {World Health Statistics 2014}. In 2012, the IP industry saw a year-on-year growth of almost 16% and is presently worth around 10% of the global industry in terms of volume and 1.4% with regards to value[15]. The strong growth of IP industry has been driven by a confluence of factors like epidemiological changes with a rapid increase in chronic, age- & lifestyle-related diseases; rising household income levels and

increasing health insurance coverage; improving healthcare infrastructure/delivery systems with a rapid expansion of the private hospital sector; and rising penetration of pharmaceuticals in smaller towns and rural areas[16,17,18,19]. IP industry has increased their productivity tremendously in recent years by increasing the number and capacity of drug manufacturing units, adhering to the norms of good manufacturing practices (GMP), keeping the cost of GD at minimum, operating on minimal profit margins, fighting fiercely to obtain manufacturing rights of generic alternatives of various PDs, adopting innovative marketing strategies for promotion of BGs, collaborating with pharma Multi-National Companies (MNCs) to make and or sell their PDs cheaply in India (contract manufacturing), and by making huge investments in the field of R&D of new drugs. Pharma MNCs have also reciprocated efforts of IP companies with huge FDIs in pharmaceutical sector, by starting Joint Ventures (JVs) with IP companies, by mergers and acquisitions (M&A) of IP companies, by bringing new technologies and PDs in India, and by differential pricing and voluntary licensing of PDs for India. Production of Pharmaceutical in India by MNCs also have advantages like availability of a large, well-educated (science graduates), skilled and English-speaking workforce; improved regulatory infrastructure; a very strong and stable democracy; and considerable financial advantages of manufacturing in India as labour costs are 50-55% cheaper, the cost of setting up a production plant is 40% lower, and overall cost of bulk drug production in India is 60% lower than the West[20].

The government has made numerous efforts to stimulate organised growth of the industry. In the pursuit of achieving global leadership in the manufacture of end to end drugs, the government unveiled its Pharma Vision 2020, which inter alia, provides for reduction in approval time for new facilities to boost investments[21]. Various financial incentives are currently given to further enhance the manufacturing capabilities of pharmaceutical companies by the central as well as various state governments. Central government allows 100% FDI in pharmaceutical sector, and has reduced Value Added Tax (VAT) and excise duty to 4% only. Some drugs like anti-retrovirals, anti-cancers etc. are fully exempted from any excise duty. Various state governments are also offering different types of incentives for establishment of pharmaceutical industry in their area like subsidized land cost, relaxation of stamp duty on sale/lease of land, power tariff incentives, concessional rate of interest on loans, tax incentives, backward areas incentives, special incentive packages for mega projects etc[22]. Further, robust mechanisms such as the Drug (Prices Control) Order and the National Pharmaceutical Pricing Authority (NPPA), Compulsory Licensing (CL) of patented drugs (PD), and distribution of UG through Jan Aushdhi Stores (JAS) have been implemented to address the issues of greater affordability and accessibility of medicines to all.

Though applicable since 2005, India granted its first and only Compulsory License (CL) till date in the year 2012 to a generic IP company Natco Pharma Ltd for sorafenib tosylate, a drug which is used in renal and liver cancers. The cost of generic sorafenib tosylate was 97% less than its patented version which is manufactured by German drug giant Bayer under trade name of Nexavar ($5500 v/s $173 per month)[23]. The CL was granted until 2020 and the reasons cited were extraordinary high cost of the drug of a public health importance and inability of the makers to initiate local production of the drug. In 2013, Swiss drug maker Novartis also lost a 7 years long legal battle when its appeal was rejected by Supreme Court of India for patent of its anti-cancer drug Glivec. In its ruling the court observed that this was an example of "incremental innovation" or "over-greening" (a term used to describe creation of a new version of a drug with only incremental modification and no innovation, in order to extend the life of a patent)[24]. In this case also, the cost of the generic version was 93% less than its patented version ($2000 v/s $140 per month). Another pharma MNC Roche has also lost patents of its anticancer drug Tarceva (generic name: erlotinib HCl) and Hep. C drug Pegasys (generic name: peginterferon α-2A) in 2012 to Indian generic manufacturers[25,26]. With these exceptional decisions, India has shown the world that it can use CL of PDs or can deny patent of a drug if necessary.

According to the WHO, each country needs to prepare its own list of such essential medicines those can satisfy the priority health care need of the population and are available within the context of functioning health system at all the times in adequate amounts, in appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford. The current National List of Essential Medicine (NLEM) – 2011 includes 348 drugs and 653 formulations and dosage forms[27]. National Pharmaceutical Pricing Authority (NPPA), which controls the drug-prices in India, notified National Pharmaceutical Pricing Policy (NPPP) in December 2012; which was implemented through Drug Price Control Order (DPCO) of 2013. DPCO-2013 placed a price limit on all the drugs on NLEM and this price ceiling was decided by average price of all brands that have a market share of more than 1% for each category of the drug[28]. Again in July 2014, NPPA ordered to cap the prices of 108 more formulations (of mostly cardiac and anti-diabetic drugs) which were not on the scheduled list of NLEM[29]. NPPA has also capped the price hike of all non-scheduled drugs to a maximum of 10% per year. To promote R&D, NPPP-2012 also provides exemption from price control for 5 year, for all indigenously developed drugs[22].

To further improve the availability of quality affordable drugs, central government has launched a country wide Jan Aushadhi Scheme (JAS) in the year 2008 where more than 500 quality UG drugs were offered through specially opened Jan Aushadhi stores throughout India[30,31]. To further improve availability of GD, government is now planning to launch its own brand of generics "Jan Aushadhi", in which center will procure medicines from public as well as from private IP manufacturers, will rebrand them under "Jan Aushadhi" and will made them available on all the retail drug stores of the country at a competitive price[32].

Recently, Medical Council of India issued a re-notification and said that the rule 1.5 of Code of Medical Ethics should be followed in its spirit. The rule says: "Every physician should, as far as possible, prescribe drugs with generic names and he/she shall ensure that there is a rational prescription and use of drugs."[33]. The Union Health Ministry is also planning to bring a gazette notification under the Indian MCI Regulations very soon which will mandate doctors to

prescribe medicines in capital letters in a "legible" manner and also mention the generic names of the drugs. Both MCI and IMA have supported the move[34,35].

As we conclude the topic "Generic drugs for public health:……..advantage India"; the global responses and overwhelming supports for generics (manufactured by India and other countries) should not be considered as an advantage to India until following issues are taken care of:

Research and Development (R&D) in India: Five leading IP companies spend approximately 5-10% of their earnings in R&D related activities but other's contributions are negligible[14]. Only patent in recent years successfully obtained by an IP company for a new chemical entity (NCE) was saroglitazar (Trade Name: Lipaglyn) which was successfully launched by Cadila healthcare in June 2013 for the treatment of Diabetes. Before that, in May 2012, Ranbaxy Lab launched Synriam (artereolane maleate plus piperaquine phosphate), a new combination drug for treatment of uncomplicated malaria[36]. Still the R&D of new drugs is nowhere near to the most of pharma MNCs which spend nearly 15-20% of their earnings on R&D and comfortably secure almost 30 USFDA patents each year in the category of New Medical Entity[37].

Dry pipeline for new and "novel" antibiotics: Infections are still one of the leading causes of mortality and morbidity in developing countries like India and to utter surprise no new classes of antibiotic have been developed for more than last 25 years[38]. Why this draught? This is because of absence of serious efforts on R&D in pharmerging (emerging pharmaceutical) countries including India, where these antibiotics are most urgently needed; whereas in the US and other indutrialised nations, innovators are not much interested in antibiotic business as only few doses of antibiotics are needed, for a few patients, for few days only and that too mostly in the countries where patients have a very poor paying capacity.

Anti-microbial resistance (AMR): Through poor practices of manufacturing and resulting environmental pollution, the pharmaceutical industry is adding to the problem of antimicrobial resistance worldwide including India[39]. Furthermore, cheaper antibiotics in India would surely mean that they are more often prescribed and consumed by patients, may be in the form of self medication or over the counter drug dispensing and very often the patient actually had no need of an antibiotic. Sometimes, a doctor in India also prescribes antibiotics unnecessarily as he does not want to overburden his/her patient with the costly investigations and or lab tests in comparison to the cost of a GD. The result: increasing drug resistance among common pathogens. And remember we have dry pipelines for antibiotics.

Slower progress in the field of pharmaceutical manufacturing: In the last decade, India has made no progress in his rankings in global pharmaceutical industry (a constant rank 13th in 2003, 2008 & 2013); this is in contrast to China (Rank-9 to Rank-5 to Rank-3), Brazil (Rank-10 to Rank-10 to Rank-8) and Venezuela (not among top 20 in 2003 & 2008, and rank 11th in 2013) in the same period[40]. According to IMS, a global market research firm, India has slipped from the 8th rank by 2016 as forecasted in 2012 to the 11th position by 2017 in its recent forecast in 2013. This is most likely due to the sluggish economy, price control, trade issues, combined with the recent devaluation in currency, against the dollar[41]. According to DGCI&S Kolkata, for a total export of USD 12.6 billion in FY12, India also imported active pharmaceutical ingredients (APIs) and intermediates worth USD 4.6 billion in FY12. China has over taken India as the main source of APIs for other countries as well due to planned and sustained support from its government in terms of infrastructure, subsidies, cheap power, transportation, dedicated capacities in voluminous manufacturing, effluent treatment facilities, and industry-friendly labor laws[42].

Quality of GDs and their manufacturing units: Many a times, Western as well as Indian media reports of poor quality of India-made generics due to non-adherence of IP manufacturers with standard norms of GMPs and or forgery of documents by IP companies to get the FDA approval for supply of drugs to the US and other industrialized countries[43,44]. These quality issues had led to confiscations or recalls or import-restrictions on the India-made generics and even in some of the cases, hefty penalties were imposed on the concerned companies[45]. Ideally, all factories manufacturing GDs as well as BDs must follow the rules of GMPs; but this is seldom true in Indian scenario. It is also revealed that many generic IP companies have set-up separate manufacturing units for supply to the western countries and for supply to the third world countries. These practices need to abolish immediately.

Corruption and poor drug regulatory mechanism in India: Kickbacks and bribes oil every part of the country's healthcare machinery[46]. On one hand, there is lack of essential medicines in the market; while on the other hand, the market is full of medicines (including FDCs) of doubtful efficacy, rationale, safety and public health relevance[47]. A famous parliamentary committee on the functioning of the CDSCO (which oversees the process of drug approval in India) in 2012 observed that many favourable opinions submitted by experts on trials of the drugs were actually based on their personal perception without any scientific evidences and these opinions were actually written by the invisible hands of drug manufacturers[48].

Compulsory licensing (CL) of patented drugs: Most of the pharma MNCs have expressed their concerns against CL of PDs by some developing countries. CL may lead to: loss of possible FDIs and collaboration with originators, intentional delay in launch of new drugs or even recall of drugs from hostile territory, reduced incentive to innovate specially for the diseases prevalent in the third world, adoption of counterproductive tactics by originators and their countries, and negative image of generic manufacturer and host country for not respecting intellectual property rights of innovators[10]. A differential pricing, voluntary licensing and or local manufacturing can become better alternatives of CL of PDs.

*Price control mechanism and maximum retail price (MRP): According to estimates only 18% of total pharmaceutical expenditure is under purview of DPCO-2013. In fact various drugs on NLEM have avoided price control through fixed dose combinations (FDCs) or nonstandard dosage/usage or newer quality like sustained-release, extended-release, slow release or controlled-release formulations. Most ceiling prices are still in the range of 200 to 4700 % of margins[7]. Only after two months of July 2014 decision for price control of 108 formulations that were not on the scheduled list of

NLEM, the government revoked the price controlling powers of NPPA in such cases[36,49].

Generic drug prescription in India: When MCI asks doctors to prescribe drugs with generic name only; this is not equal to prescription of generic drugs only but this simply means that doctors should write generic name of a drug and than a drug retailer will choose which type of drug to dispense. It can either be a PD or a BG-I or a BG-II or an UG. One would wonder that it's the Indian government who fixes the MRP of a drug in India and once approved, how they can ask the doctors not to write drugs on such an MRP[33].

CONCLUSION:

So, in short, the picture is not as bright as it seems in India as we are heavily dependent on foreign MNCs for new innovative/pioneered drugs and APIs; quality of India-made generics is questionable sometimes; pharma MNCs are highly unsatisfied with India's over-protective approaches in drug pricing and patent issues; and India is having a slow progress in generic drug manufacturing in comparison to other pharmerging countries.

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