Grant of approval to the premier drug policy by the state cabinet has led to several apprehensions pertaining to the impact of generic drug prescribing on pharmaceutical trade in the state. Misperceptions surrounding generic drugs are creating fears that medical representatives may be rendered jobless and pharmaceutical retailers/wholesalers of branded drugs may have to wind up their businesses. Widespread myths and misconceptions among common masses, pharmacists as well as doctors regarding generic drugs have only been compounded by the series of newspaper articles propagating incorrect information about generic drug use and ignoring all other aspects of the policy which are equally important from the point of view of common consumers. Generic drugs are those that have gone off the patent protection, are sold on the name of their active ingredients and are the same as that of their branded counterparts in terms of dosage, safety, strength, purity, stability, quality, performance, route of administration and intended use. Most of the apprehensions related to generic drug prescribing clause of the state drug policy pertain either to quality and efficacy of generic medicines or the impact of generic drug prescribing in government health facilities on pharmaceutical trade. This article attempts to allay such apprehensions on grounds of logic, reasoning and facts.

Need for Generic Drug Prescribing in Government Hospitals:
Generic drug prescribing provision of the recently approved drug policy of J&K state has come under severe criticism from several quarters mainly raising doubts about the quality, feasibility and efficacy of generic medicines particularly in our settings. Even more vehemently questions have been raised regarding the need for introducing generic drug prescribing in our government health facilities. Actually such a need arises for the cause of promoting access to medicines that includes enhancing both availability and affordability of drugs to the patients visiting government health facilities for treatment. According to World Medicines Situation Report published by WHO in 2004, an estimated 2.1 billion people worldwide (one third of global population) do not have access to medicines and use of generic medicines whose sale comprises 30% (about 80 billion USD) of the total global drug sales, can improve that dismal scenario. As per this report, within India, an estimated 499-649 million people (50% to 65% of the population) do not have regular access to essential medicines. An estimated 24.21 lakh people (21.63% population) in J&K state live below poverty line and it is these people who cannot afford costly branded medicines. That is why National Human Rights Commission, World Health Organization, several expert committees and the National Commission for Macroeconomics and Health have unanimously advocated use of generic medicines in government hospitals. Price difference between generic and branded drugs ranges anywhere between 10% to 5000%. Just to cite an example one vial of generic 1gm cefoperazone + 1gm sulbactum costs Rs. 140 as against Pfizer’s Rs. 500, BIPL’s 458 and CMG Biotech’s 456 rupees. Similarly a strip of branded Cetirizine containing 10 tablets costs more than 30 rupees as against 50 paise for the same strip in generic form. At present there is no government price control on about 75% of the retail branded pharma market within India that often leads to overcharging by pharmaceutical companies. That is why WHO has identified use of generic drugs as one of the major components of any National Drug Policy. These facts elucidate the need to have generic drug prescribing in our government hospitals too.

In India at present we have National Drug Policy of 1986 in vogue that has been modified only once in 1994 and since then as many as three attempts to promulgate a new National Pharmaceutical Policy in the years 2000, 2002, 2006 have been foiled by the pharmaceutical corporate world just to ensure that only 75 drugs remain under Drug Price Control Order, 1995 (whose prices are fixed by the government) and a vast majority of other drugs (more than 500 in number) including Essential Drugs remains outside the purview of DPCO so that they could themselves fix their prices as per their own whims and fancies. Supreme Court of India in Union of India vs. Glaxo Consumer Healthcare Ltd. & Ors. [2009] 10 SCC 736 also directed the government to promulgate a single national policy which can ensure that all essential drugs are brought under the ambit of Drug Price Control Order, 1995.

**Generic Drug Prescribing in J&K – boon or bane?**
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India vs KS Gopinath, has, on March 10, 2003, made an order directing the union government to consider and formulate appropriate criteria for ensuring that the essential and life saving drugs do not fall out of government price control.

**Quality Standards of Generic Drugs:**
There is a common perception among people as well as medical professionals that the quality and efficacy of generic medicines is doubtful. However fact of the matter is that if the government follows standard guidelines of pre-qualification and post-qualification of suppliers and strictly adheres to the technical specifications as has successfully happened in case of Tamil Nadu Medical Supplies Corporation, there is no reason why government can't procure good quality drugs. If India can supply quality generic medicines to the extent of 22% of entire global generic market and if highest number of USFDA approved generic manufacturing units outside USA are based in India, what makes it impossible to procure world class quality generics from such approved companies within India? It all depends upon the will and intent of procurement and enforcement agencies of the government as to what quality standards they can maintain for generics. More than 75% of all the prescriptions in US and 83% prescriptions in UK contain generic medicines nowadays, mostly manufactured by Indian Pharmaceutical companies but unfortunately within India a ghost has been carved out of generic drugs and lot of myths and misconceptions have been floated regarding their quality and efficacy just because the prescriber-manufacturer nexus is too deep and corporate lobby pumps huge money into the promotion of their branded products. In a recent study it has been suggested that more than 40% cost of medicines goes into bribing the prescribers and more than 500 pharmaceutical companies within India own central government a mammoth amount of Rupees 4000 crores on account of overcharging on branded medicines and now GOI is finding it hard to recover such huge dues from the manufacturers.

It is quite possible for the state government to ensure standard quality of generic medicines by having stringent quality control measures, foolproof quality assurance mechanism, well-defined, transparent procurement and tendering policy, by adopting efficient technical specifications, pre-qualification and post-qualification criteria for drug supplier selection, by having in-house quality control cells in all major hospitals, by ensuring pre-shipment as well as post-shipment analysis of drug consignments, by taking samples randomly from all warehouses for testing, by having an effective drug problem reporting and recording mechanism, by making onsite periodic surprise inspections of manufacturing premises, by decoding the drug samples before sending them to government and private empanelled laboratories for testing, by validating the testing quality of these laboratories, by blacklisting the suppliers whose drug samples fail upon testing and putting their names on official website of the health ministry, by adopting a perpetual and seamless quality assurance mechanism in all healthcare institutions of the state. The widely held belief that generic medicines are sub-standard is not based on facts because this notion has been nullified by a substantial number of BA/BE (Bioavailability/Bioequivalence) studies on generics. Indian generics marketed in US have also been found to be bioequivalent, having similar quality, safety and efficacy as branded drugs, by the USFDA and then only given marketing approval within US.

Traders fear that unscrupulous manufacturers will quote lowest rates while filing tenders and then make up for the losses by supplying medicines of inferior quality. However that is not likely to happen because drug policy envisages a two-tier tendering system for the procurement of generic drugs wherein value for money will be the primary criteria for selection rather than lowest bid. It will be a double-envelope system whereby first envelope will contain the technical bids and only those suppliers who fulfill the technical criteria set by the purchase committee would be called for the price bid through second envelope and it is at this level when the lowest bidders will be awarded the tenders. Thus quality parameters will receive priority over price even though both criteria will be utilized to select the best and most economic suppliers.
Pharmaceutical traders apprehend large scale job losses:
Medical Representatives, stockists and super-stockists associated with the medical trade in the state claim that more than 80% of pharmaceutical trade in Kashmir depends on government sector and therefore generic drug prescribing will wreak havoc to the trade. As a matter of fact, total outlay on drugs and instruments in budget estimates for the year 2012-2013 for all the government hospitals of the valley does not exceed Rs. 25 crores (as reflected by the official website of the J&K Finance Dept.)\(^{13}\) whereas it has been officially declared last year that medicines worth Rs. 400 crores are consumed annually in Kashmir valley alone\(^ {14}\). By that measure, government supply constitutes only 6-7% of the total drug market in the valley. Therefore it is practically not possible that 80% of the total pharmaceutical trade would be dependent on a segment that comprises only a miniscule of the entire medicines market of the Valley.
Pharmaceutical traders of the state also claim that generic drug prescribing will make more than 10 lakh people associated with pharmaceutical trade jobless in Kashmir valley alone\(^ {15}\). Again it is beyond comprehension as to how 10 lakh people can survive on a meager amount of Rs. 25 crores for the whole year, which is the total allocation for drugs and instruments in all government hospitals and departments of the valley. That means each individual of the pharmaceutical trade dependent on government medicine supplies is living on a mere Rs. 250 per year. Even if we reduce the total number of dependents from 10 lakh to just 10000, per head share does not exceed Rs. 25000 per year. Is it practically possible for a Medical Representative or a supplier to survive in today’s times on just 25000 rupees for the whole year?
Traders claim that generics have high profit margins due to which retailers benefit and not the patients. However generics are cheaper not because of any misperceived inferior quality but because huge expenses incurred on the Research & Development, brand promotion, publicity & marketing, patent royalty of branded medicines are saved completely. Drugs manufactured in India are classified as Branded-Generics (those generics that have gone off the patent but still are sold on a brand name) and Generic-generics (generics that have gone off the patent and are sold on their chemical names), both of which are available to the patients at the same cost, but there is huge cost difference in the two for a retailer. Therefore if hospitals purchase generic-generics directly from the manufacturer there will be cost saving for the patient to the extent of 70-80% and drugs will become available to them at as low as 10-20% of the market prices. At present only branded generic drugs are available in our private as well as hospital drug stores. Therefore it is high time to promote use of generics. New drug policy encourages direct purchase of medicines from manufacturers so that costs incurred by middlemen and supply chain stockists can be saved and the benefit of these savings transmits directly to the patients visiting government hospitals.

Availability of generic drugs at government health facilities:
Opponents of the drug policy believe that existing quality and availability of drugs in government hospitals is pathetic that will only worsen after introduction of generic drug prescribing. There is no second opinion in the fact that existing system of medicine procurement of the state is full of flaws and has miserably failed to make drugs available to patients on hospital drug counters even for a considerable portion of the year and the drugs supplied to patients free of cost at present at government health facilities lack quality too because there is hardly any quality control mechanism in place but things are supposed to change under the new drug policy regime. Concept of Essential Drug List will minimize the number of drugs to be procured to just 348 and will thereby ensure economies of scale so that all necessary medicines of standard quality can be made available throughout the year within hospital pharmacies. However for that to happen, an efficient procurement and stringent quality control mechanism has to be in place. Drugs have to be procured through an autonomous, constraint-free mechanism that will function in a completely transparent fashion and will be devoid of any political interference in decision-making. Tamil Nadu Medical Supplies Corporation Model\(^ {16}\) has shown the way how it can be achieved and that is the reason why this model has been appreciated, approved and recommended for all Indian states not
only by the Government of India but also by the World Health Organization. Affluent people who prefer to use branded medicines over generics will be free to purchase such medicines from the open markets since generic drug prescribing policy applies only to government sector. Prescribing and sale of branded drugs will continue unabated in private sector even after new drug policy is implemented in the state.

Prescriber versus Dispenser Conflict:
Further it is feared that generic drug prescribing will disempower qualified physicians from exercising a choice of brands and empower unqualified chemists to substitute prescribed generics with generics of their own choice on profit basis. However, inherent design of the new drug policy is such that all generic medicines listed in the Essential Drugs List will have to be kept available for distribution among patients on hospital pharmacy counters within all government health facilities throughout the year without allowing any stock-outs to occur at any point of time, so that all the prescriptions whether belonging to in-patients or out-patients can be dispensed within the hospitals and there is no need for the patients to purchase branded or generic medicines from outside the hospitals. Use of an Essential Drug List of only 348 drugs instead of more than 30,000 formulations available in the market can ensure availability within hospitals throughout the year. Therefore it all depends on how well government agencies are able to implement the policy provisions and maintain adequate drug stocks within hospitals throughout the year without allowing any shortages, that will determine whether chemists operating outside the government hospitals will get any opportunity to substitute prescribed generics with generics of their own choice driven by large profit margins for the retailers or not.

Refilling of Generic Prescriptions:
Some people also apprehend that refilling of prescriptions of patients from far flung areas will become difficult since generic drugs are not available in the open markets. However such issues can be taken care of by the prescribing physicians who may prescribe as per the patient's short-, mid- and long-term needs so that patients are able to keep adequate stocks with them depending on their distance from the healthcare centres. Keeping in view exceptionally low cost of these drugs, it won't be a problem for the patients to purchase a few extra doses. Further all patients with common, speciality or rare diseases have to revisit their physicians for consultation when they can refill their prescriptions. Adequate number of drugs listed in state EDL will have to be kept available at all district level healthcare facilities throughout the state so that patients do not face any difficulty on account of their access and availability. Simultaneously, as per the approved drug policy, the State Essential Drug List will be categorized according to the levels of health care facilities like primary, secondary and tertiary. There are some drugs which though not listed in the essential drug list are required for specific diseases/exceptional cases. Keeping this in view, approved drug policy provides that a supplementary drug list shall be drawn by the State Drug Committee and a provision of grants not exceeding 10% of the allocated budget for drugs shall be earmarked for purchase of drugs in the supplementary drug list.

Spurious Drug Trade and Generic Medicines:
Some people feel that spurious drug trade will flourish due to generics. Spurious or counterfeit copies are usually manufactured for branded drugs that are costly and not for generics that are so cheap that even manufacturing their spurious versions will not make much cost difference from the original. Usually 500 or 1000 rupee notes are counterfeited rather than 5 or 10 rupee notes because counterfeiters want instant huge gains and faking cheap generics will not fetch them any money worth all the pains and risks they take to manufacture and market them. Furthermore, in regard to curbing the menace of spurious/counterfeit/sub standard/misbranded/ adulterated drugs in the state approved draft of the drug policy envisages that an intelligence-cum-legal cell shall be established in the office of Drug and Food Control Organization, J&K to facilitate busting of spurious
drug rackets and their prompt prosecution and that the efforts shall be made to provide incentives to informers giving information about spurious drugs. It also mentions that adequate steps shall be taken to ensure proper implementation of drug regulations especially with regard to offences related to adulterated or spurious drugs\(^7\). Therefore the belief that spurious drug trade will flourish due to generics is not based on logic or facts.

**Preference to Local Manufacturers during Procurement:**
New Drug Policy envisages to encourage, promote and support local manufacturers of pharmaceuticals in the approved drug policy however this is not a good drug procurement practice as per international norms and well-established standards since it tilts the balance in favour of the local manufacturers and discourages reputed pharmaceutical concerns from outside the state from participating in competitive bidding process. Moreover it is true that local drug industry is virtually non-existent in the state and the few odd small scale units operating from within the valley cannot cater to the generic drug demands of all the state government hospitals. Government must procure medicines through a completely transparent and fair competitive bidding process that equally encourages local as well as non-local bidders of repute.

**Generic Prescribing in our settings:**
Large section of the society believes that generic prescribing is an alien concept that can work only in developed nations like US and UK and not in our poorly regulated, corruption-marred settings. It is understandable that situation in our part of the globe is no match to that in US or UK, which results in numerous apprehensions about the success and implications of generic drug prescribing. Even though generics have proved to be a big success everywhere else, in our part of the globe where there is large scale corruption and drug markets are poorly regulated showing little compliance with norms, enforcing genuine generic prescribing and sale is a huge challenge for the government agencies. To address such predicaments, examples of several Indian states like Delhi, Tamil Nadu, West Bengal, Rajasthan, Himachal Pradesh, Chattisgarh, Kerala, Karnataka, Uttarakhand can be cited that have shifted to generic prescribing in government hospitals successfully and tremendous benefits have been recorded in every aspect of drug use. The system has resulted in a fall in drug prices to the hospitals in these states by 30-40 per cent\(^8\), better quality assurance and less duplication of effort. Same is the case with another resource-constrained country like Bangladesh that has also made good progress in this direction. Initially there is skepticism but with effective implementation of the policy, all problems are gradually sorted out. However necessary pre-requisite is that there has to be effective and foolproof implementation of the policy by the government agencies, devoid of any corrupt practices. If proper implementation of the policy fails, generic prescribing cannot be of any help.

Lastly there are some studies that have advised against sudden transitions from branded to generic therapy, particularly in case of drugs having narrow therapeutic/safety index like anti-epileptics, digoxin, warfarin, levothyroxine etc\(^9\). There are also some studies contesting the therapeutic equivalence of some generics. However the widely held belief that generic medicines are not equivalent to branded drugs is not based on facts because this notion has been nullified by a substantial number of BA/BE (Bioavailability/Bioequivalence) studies on generics. Indian generics marketed in US have also been found to be bioequivalent, having similar quality, safety and efficacy as branded drugs, by the USFDA and then only given marketing approval within US. Between 2003 to 2008, in programmes supported by donor organizations like the Global Fund, Indian generic drugs accounted for more than 80% of the drugs used to treat AIDS, including 91% of pediatric antiretroviral products, and 89% of the adult nucleoside and non-nucleoside reverse transcriptase inhibitor markets\(^10\). India is also the most important source of generic drugs for cancer, heart disease, and other diseases and conditions. That would not have been possible had the generic versions not found to be bioequivalent to their branded counterparts.
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Conflict of Interest: None

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