EXPRESS HEALTHCARE

Genericisation evokes fierce debate at third edition of Vantage Point

By Lakshmipriya Nair and Mansha Gagneja on June 8, 2017

Panelists divided on the impact of the push for generics, many laud the intent but remain sceptical of consequences

Dr Milind Antani

A fiery debate on 'Genericisation: Panacea or Pandora's Box?' ensued at the third edition of Vantage Point, Express Pharma's platform to discuss and deliberate on Indian pharma sector's most pressing and controversial topics. Partnered by Wellness Forever, the event was held at Sofitel in Mumbai. An eminent panel deliberated on the implications and possibilities of the Centre's push towards genericisation of pharma brands, in a very interesting and insightful session, moderated by Dr Milind Antani, Head, Pharma and Life Sciences, Nishith Desai Associates.

The panel comprised Dr Amar Jesani, Editor, IJME; Dr Jayesh Lele, National Secretary – IMA Board of India; Milind Mangle, Internationally Certified Coach and Consultant, Angle Consultancy & Services; Vaijanath Eknath Jagushte, Treasurer, Chairman of Legal Affairs Committee —AIOCD & MSCDA and Treasurer of MSCDA; Priti Mohile, Managing Director, MediaMedic Communications;
Dr KS Sharma, PG Committee Member, Medical Council of India MCI and Director Academic Tata Hospital; Daara Patel, Secretary General, IDMA and Dr Suleiman Merchant, Dean, Lokmanya Tilak Municipal General Hospital and Medical College.

Dr Antani drew out the panelists to share their views candidly and discuss the ramifications of a mandate to prescribe only generic names of drugs. He steered the debate to touch upon lesser discussed points and look at the issue in a more detailed manner. He also threw light on many legal aspects of the issue and explained the various grey areas to give more clarity on the same. Dr Antani, in the course of his moderation, quipped that the Indian lifesciences industry is facing a challenge between choosing what is ethical and what is legal.

Industry representatives were openly critical of genericisation. They viewed the move with disfavour and highlighted various pitfalls which would arise if genericisation became the law. Do all generic medicines give the same results as their branded counterparts? Are enough generic medicines available in market? While focusing on price, how do we not lose sight of quality?These were some of the questions posed by experts and veterans during the debate.

At the same time, there were panelists like Dr Jesani who was totally in favour of prescribing generics. He outlined the various advantages in terms of access and affordability of medicines. He said that if there was political will and collaboration between stakeholders, then genericisation could indeed be a panacea and create significant positive impact for patients. At the same time he admitted that there is a need to have better monitoring mechanisms in place to ensure effective implementation of the government's push towards generics.

Opining that genericisation is a populist move, Dr Lele questioned the preparedness of the government to implement it effectively. He said that quality can be a concern in such a scenario as the industry and medical fraternity is ill-equipped to deal with genericisation. He lauded the intent of the government but expressed reservations about effective implementation of the move.

Mangle pointed out that this is a very multi-faceted issue and would have wide-reaching implications. He explained the rationale of the government behind pushing generics and stated that though the intention was to introduce a panacea to many problems faced by healthcare industry today, inadvertently opened a Pandora's Box. He said that our public and other stakeholders are still uninformed about various issues and hence not ready for a step like genericisation. He pointed out the various complexities arising from the move and said that lack of accountability is one of the major concerns in this situation.

Mohile was in favour of genericisation but she too had doubts about the step being successful in achieving its objective. As a communication specialist, she threw light on how marketing and PR would change in times of genericisation and its effect on patients. She also said that information about quality will become paramount in future.

Jagusthe expressed concerns about ensuring quality and said that it is a premature move. He pointed out that there is no standardisation in India as far as quality is concerned. He opined that unless quality is assured through proper regulations and infrastructure, enforcing prescription of only generics is not a good decision. He lauded Jan Aushadhi as a good initiative to make medicines available but recommended strengthening it with better economic policies to make it sustainable and extend its reach.

Dr Sharma gave instances of how genericisation can fail in implementation and raised concerns about quality, accountability and efficacy. He said that the government's intention to nullify the nexus between the medical fraternity and pharma companies might not really succeed as the wrongdoers might find ways to circumvent the move and continue with the malpractices. He also pointed out to various grey areas which may prevent the move from being a beneficial one, for instance, crosspathy practitioners do not have to adhere to these guidelines.

Patel was emphatic that 'generics only' is a decision which will not serve any objective. He stated that other measures to reduce prices might be more effectual and claimed that the industry would support the government if they come up with better strategies to serve the masses. He recommended slashing taxes of essential medicines as a measure to reduce prices of drugs.

Quality was a concern raised by Dr Merchant as well. He said that until the right
standards, infrastructure and regulations are put into place to determine the efficiency and efficacy of drugs in India, genericisation will not be successful. He was also of the opinion that it is an idea whose time has not arrived yet.

Thus, the panel was divided in its opinion about government's decision to promote generic medicines. The panel discussion was followed by a Q&A session. Viveka Roychoudhury, Editor, Express Pharma and Healthcare posed the first question. She asked whether seminars held for associations help in maintaining the quality of medicines and in educating patients to take a good decision? To which Patel responded that they have already got an approval to add a topic on generic medicines to the existing seminars.

SR Vaidya, Chairman, SME committee, IDMA, suggested that there must be seminars held on quality of excipients as they constitute 95 per cent of the drug. He insisted on making pharmacovigilance activities mandatory which can increase the quality standards of generics.

Deepak Paliwal, External Advisor, GSK, London, connected with the audience and panelists through Skype. He was in favour of the government's move and threw light on a pilot project in the state of Andhra Pradesh where pharmacists are prescribing generics for past three years. He further clarified the government's motive behind mandating writing the generic name in capital letter is to ensure more readability among patients and pharmacists.
Akash Rajpal, MD and CEO, Ekohealth Management Consutants, raised a set of legal questions related to the liabilities of doctors while prescribing medicines. He asked, "Is a doctor liable when s/he prescribes a branded medicine of their choice and something goes wrong? Also, if the doctor is not liable in this case, then how can s/he be responsible when s/he prescribes a generic medicine? Are there any drugs available at pharmacies that are not FDA approved?"

Mangle replied saying that as of now, doctors can be held accountable for the various brands they prescribe. While prescribing generics, the patient might not know who to hold responsible as the liability might keep shifting among various stakeholders.

Further on, the panelists highlighted the importance of bio-equivalence studies and the need for standardisation to build trust. On the contrary, Dr Jesani raised a point that in case of substandard drugs, the manufacturers are to be held liable and the regulators like CDSCO should be more attentive towards any spurious drugs available in the market. He also suggested that more investments need to be made in order to bring each company under their surveillance.

Sripad Desai, Americares, inquired that even if doctors prescribe a generic medicine, will the pharmacists be able to dispense branded ones? The panelists expressed that substitution is against the law and there is a need to take a few learnings from the US where unique codes are allotted to each formulation.

Payal Laad, Professor, Community Medicine, Sion Hospital, referred to Bangladesh's drug model and asked what can be the takeaways for India. Patel, informed that the Indian state of Rajasthan has a similar policy but, there are few hurdles faced while extrapolating these schemes across India.

Dr Gopal Dabade, President, Drug Action Forum of Karnataka asked whether generic medicines can be available at affordable prices, to which the panelists responded that there is an urgent need to tackle the nexus between manufacturers, doctors, and chemists for patients' benefit.

The event came to close with the panelists unanimously agreeing that patients' well-being should be safeguarded at all costs. Therefore, before the government mandates generication of medicines, they need to put in place the required processes to ensure that quality generic medicines are made accessible for all.

lakshmipriya.nair@expressindia.com / *mansha.gagneja@expressindia.com*