Pragmatic trade policies & focus on quality essential to create innovative drugs ecosystem in India: Experts

Speaking at a panel discussion on ETPharma Tech Innovate Conclave, industry experts have suggested the policy makers and regulators to align with some global regulatory practices and adopt a pragmatic approach towards innovations, trade relations for providing access to best medications along with the over development of manufacturing infrastructure in the country. One of the panelists has also suggested to include the quality aspect along with price for projects under the Make in India initiative.

Mumbai: At a time when digital innovations are sitting at the driving seat of the global marketplace irrespective of the nature of industry, when it comes to pharma there is still a palpable mistrust among quality controllers and regulators with respect to their impact over the quality, safety and efficacy of drugs. However, there is no escapable route from the ongoing digital wave and adopting it into the established framework is chorused by many experts as the only way forward.

But instead of merely adopting, it is also imperative to extract a value proposition from this transition, which necessitates fostering a sense of camaraderie between the innovators and regulators where patient centricity takes precedence, and digital tools act as facilitators.

To explore the scope of such challenges, associated complexities and bringing various stakeholders on the same page by identifying their potential solutions, at the inaugural edition of ETPharma's Tech Innovate Conclave, convened a panel discussion on 'Innovations and Regulations - a tightrope walk"

The expert panel for the discussion comprised Dr Sadanand Kulkarni, Head-Medical, Regulatory, Vigilance, Quality (South Asia), Fresenius Kabi India; Dr Priya Chatterjee, Head Regulatory Affairs – South Asia, Bayer; Anurag Agrawal, Vice President – Regulatory Affairs, JB Pharma; Dr Pratik Shah, Vice President Medical Affairs, Bharat Serums and Vaccines Limited and the session was moderated by Dr George Patani, Vice President, IDMA- West Zone.

Starting the conversation Dr Priya Chatterjee, Regulatory Affairs head of South Asia division of an MNC drug maker Bayer credited regulators for proactively revising the norms and flagged the Industry's slow pace in adopting those evolving norms.

Dr Chatterjee emphasised, "Regulations and innovations go hand in hand and at times regulations set the way for instance the medical device industry in India is still getting upgraded to the new format but the device regulations have been in place since 2017, some benchmarks were set up and Similarly the FSSAI (Food Safety and Standards Authority of India) 2012 guidelines which made a demarcation between nutraceuticals and drugs."

"For emerging sectors like e-pharmacies and CGT (Cell Gene Therapies) the government has introduced draft guidelines while for the later regulators are in the process", she added.

Voicing the same, Anurag Agrawal, JB Pharma's Regulatory Affairs, Vice President said," Continuous manufacturing in pharma has been in existence for the past two decades but it was more of a traditional set up and the process control were not much automated but the ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) guidelines on continuous manufacturing provides a proper roadmap on how organisations can integrate them as platform technology and have a definition of batch. Hence, due to such measures in the last 10 years the FDA has received around 50 applications for continuous manufacturing."

Uncovering the other side where the innovators took a lead from regulators, Dr Sadanand Kulkarni, Regulatory head at Vigilance, Quality (South Asia), said, India is evolving as an Innovation hub and because of which many companies from the regulated markets are establishing their capacity centers in the country.. regulators should also devise some plans which can further help both domestic and global innovators."

Sharing some developments from the vaccines segment, Dr Pratik Shah, Vice President Medical Affairs, Bharat Serums and Vaccines Limited, noted, regulators like FDA, EMA are coming up with their own guidelines if there is an emergency and there is time constraint vaccine makers can present their data and obtain approval even with slightly less evidence. The Indian regulators are also moving in the same direction COVID vaccine is one such example in this regard."

There is also a challenge of creating an ecosystem which is beyond the rapidly changing political beliefs, responding to this query Dr Kulkarni underlined, "Whether we like it or not China has been a major API, technology supplier and in medical devices they are way ahead and if the political thinking of the policy makers over plays that becomes challenging."

Hypothetically framing a scenario flagged, Dr Kulkarni, said, "If we decide to not import Chinese products for our hospitals it will create a big hindrance because we could even face the reciprocation from the other side as well and local innovators might not be welcomed by global players which would eventually deprive our poor patients from accessing the innovations taking place in the rest of the world."

> "There should be rules, regulations and compliance norms but largely as a principle we should encourage innovations from the regulatory perspective for the overall development of an ecosystem for both pharma and medical devices", Dr Kulkarni added.

Adding to these points, Dr Priya Chatterjee elaborated, "While we (government) want to support our domestic industry, we also have to ensure access to best medication in order to do so we have to create a balance between global innovations and domestic products."

She also urged to review the Made in India initiative by attributing that "sometimes it is only the price which gives entry in the tender of the policy but the stakeholder should look at the quality aspect as well so that patient safety and wellness becomes center of the discussion."

For creating the regulators a positive force to support innovation, Dr Shah echoed that regulators too have difficulties in keeping pace with innovations but through better coordination and collaboration this could be overcome with time.

He shared, "At times biopharmaceutical companies in India have to provide everything including the testing method so that the regulators can test and validate the results. Hence we (regulators and industry) need to be prepared for the coming changes because developments like AI will keep on happening and companies should start considering self-regulations also."

Concluding the discussion Agrawal remarked that, "Currently we have a product based regulatory framework across the globe due to which every new innovation like new technology, process control etc. which is totally counterintuitive to the Industry's approach which wants to innovate and move faster into the market."

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