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Clear regulatory pathway for diagnostics kits

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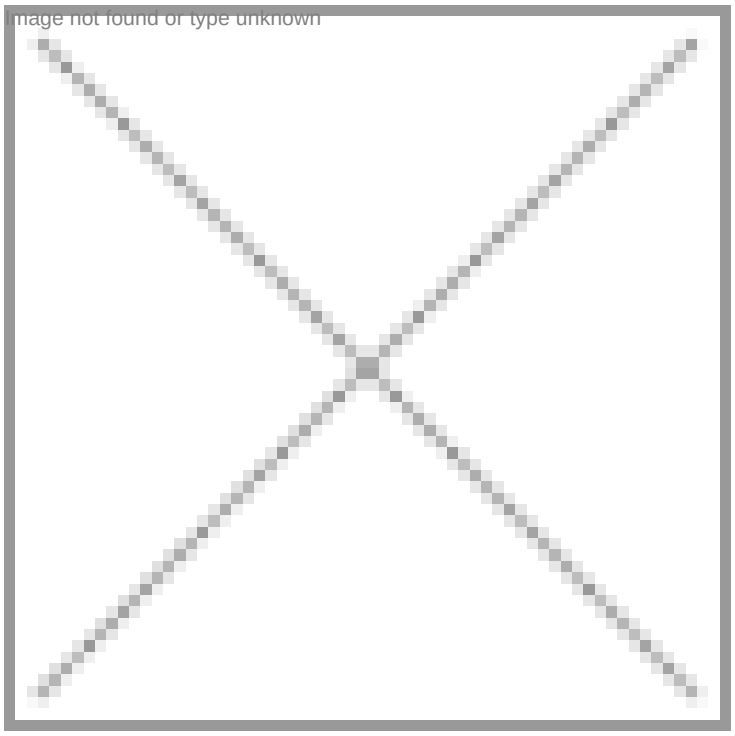

Despite increasing emphasis on strengthening infrastructure for healthcare, the Indian government has overlooked the need to chalk out a well defined regulatory pathway for diagnostic products, leaving many domestic companies lurching in the dark

Elisadiag Image not found or type unknown year back, a couple of days after the Indian Finance Minister presented the budget, a renowned expert from the diagnostic sector shared his disappointment with *BioSpectrum* about the budget failing to address the sector's needs. He said, â€œWe have been a neglected sector. We are yet to have a separate set of regulatory guidelines for this sector.â€? One year hence, the situation hasn't changed. Indian diagnostic industry comprises of biochemical testing, hematology, microbiology, immunology, coagulation, urinalysis, critical care, and molecular diagnostics. The Indian diagnostics market witnessed a growth of 22 percent from 2,000 crore to 2,440 crore in 2010-11.

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Despite the prime significance of this sector, a well-defined regulatory pathway for diagnostic products is awaited. Due to the lack of a regulatory legislation there is no clarity on the classification and requirements for approval of diagnostic products and novel medical devices in India.

Need for a change

Experts from the diagnostic sector are now clamoring for a change in the way approvals to such products are given by the drug controller general of India (DCGI). At the time of approval, diagnostic products and medical devices are categorized into critical and non-critical diagnostics. Any diagnostic tool developed by an indigenous company or academic institution has to go through a validation process conducted by an independent, DCGI approved testing lab such as National Institute of Biologicals (NIB), apart from the in-house validation procedures conducted by the company itself. For other products, it needs to be proven that there are same products approved in India. Despite the huge technological differences between the two, diagnostics are still treated as drugs by the DCGI.

Shama Bhat, chairman and managing director, Bhat Biotech, says, â€œIf it is a new product then you need to get a no objection certificate (NOC) from the DCGI. The major hurdles are the lack of knowledge of the products by the DCGI. Most of the officers are pharma people and they lack the knowledge of diagnostics.â€?

Today, the DCGI recognizes primarily HIV, Hepatitis B and C blood grouping, and Syphilis kits as the ones needing serious

licensing and regulation. BV Ravi Kumar, founder, chairman and managing director, Xcyton Diagnostics, says, â€œRegarding the rest of kits, there are neither guidelines nor any institutes, with known positives and negatives to be tested. As a result, the Indian companies innovating new diagnostics have a great difficulty in catering to overseas market opportunities as the country of origin has no well laid out procedures.â€? Dilip G Tripathi, managing director, Tulip Diagnostics, agrees with Kumar and says, â€œToday there is no clear definition of what can be defined as critical and non-critical diagnostic products. So every time we go to the DCGI for an approval of our product, it is randomly given a critical or a non-critical status without giving any clear reason for their classification.â€?

Obscurities also lie in the validation processes. Satish Gupta, deputy director, National Institute of Immunology, says, â€œI agree that an independent validation is an important process as an in-house team can sometimes be biased. However, there is no clear pathway by the government on what and how exactly should the validation process be carried out. The DCGI has not assigned a team for the task. Companies have to scout around for institutes or hospitals to test and validate their tools. This leads to undue delays in bringing the product to the market.â€?

On the contrary, products which are imported and marketed into the country do not have to go through these procedures because they have been approved by globally accepted regulatory standards. Indian companies beg to differ as they claim that given India's diverse population, validation becomes a prerequisite for all companies. Pradip K Desai, founder chairman and director, Span Diagnostics, mentions, â€œValidation, indigenous or imported, is very important because it may so happen that it might be effective on one section of the population while it may not be effective on the other due to India's large genetic diversity. Government needs to establish a clear pathway for such evaluation processes.â€?

The quality of the testing labs is also questionable. Ravi Kumar adds, â€œThese are academic institutes not geared to conduct these kinds of evaluations on a regular basis, and hence their validation processes cause unusual delays. This also vitiates the results due to institutes' bias of what?the specifications of the test should be than what the market requirement is.â€? For instance, kits recently tested at NIB for quality assessment were pulled up by the DCGI on grounds of quality. Kumar informs, â€œDue to serious deficiencies in the procedures many companies suffered, as some batches got unfairly labeled as 'not meeting specifications'. Now, National Aids Control Organization (NACO) has finally commissioned many institutes across India such as National AIDS Research Institute (NARI), National Institute of Mental Health and Neuro Sciences (NIMHANS) to conduct quality evaluations for the batches.â€?

The lack of clear specifications also allows for many products, which are not classified by the DCGI, to get into the market without any approval. Says a source on the condition of anonymity, â€œMany a times new products cannot be introduced to market as they don't fit in any regulatory classification. Thus, lack of such a regulatory framework and standards in India brings a large disparity on the quality of products. Many products are available in India without approval.â€? Sandeep Saxena, founder CEO, Acton Biotech, mentions, â€œThis puts pressure on the buyer to first test the product in-house before using it on patients. And in turn the buyer expects free samples from the seller. That delays the sales cycles and increases costs.â€?

Separate regulatory authority

A recent hurdle which is being faced by segments across the biotech sector is the frequent changes of the DCGI. â€œIn the last couple of months, two DCGIs have been changed who were there for a temporary period of time. This has led to a lot of our approvals getting delayed because by the time we submitted our approvals to one DCGI, it was time for him to move on and we had to repeat the whole process from the start when the new person came,â€? adds Tripathi.

Speaking to *BioSpectrum,* most of the industry experts from the top indigenous companies demand that there should be a separate regulatory authority for approving diagnostic products where specific dossiers can be submitted. Saxena says, â€œIt is high time DCGI looked beyond drugs. They need separate teams for vaccines, devices, and diagnostics.â€?

Many domestic companies have also said that there is a dire need for a central testing lab for diagnostic products which can come about only when there is a clear well-defined pathway for the sector.

The Association of Diagnostic Manufacturers of India (ADMI), an association of Indian in vitro diagnostics manufacturers,has approached the government with various proposals for reforms , but it has not received any response so far. To bring about uniformity in classification and specifications among all diagnostic products, the association had made a list of above 100 products along with their respective classifications and specifications. Tripathi, who is also the president of the association, recalls, â€œWe had collected and collated a list of diagnostic products from all the companies in India along with their specifications and submitted to the DCGI for reference, but there was no result. It took us one year to collate such data but the entire effort was wasteâ€?

India is at an inflection point today when it comes to innovation in diagnostics. Investments, both in terms of time and money, towards this sector by the Government of India will not just lead to a spurt in affordable new products , but also bolster the quality infrastructure in the country.

Nayantara Som Banerjee in Mumbai