

Medical device MNCs run the show at global standards organisation meetings, complex rules hurt MSMEs

Arun Sreenivasan, New Delhi, Friday, April 20, 2018, 08:00 Hrs [IST]

The Central government's disinterest in the international standard making process and the MSME sector's failure to understand the procedural complexities are helping multinational medical device majors influence global standards organisations and change the rules of the game to their advantage, say industry experts. The immediate implementation of the national strategy for standardisation of products and services, floated by the ministry of commerce last month, is an imperative step to ensure Indian companies a level playing field, they say.

Multinational medical device makers, which have petitioned the Office of the United States Trade Representative over India's pricing policy and triggered a review of the country's eligibility to enjoy Generalised System of Preferences (GSP) concessions, have been repeatedly using their clout to amend global technical standards. The latest issue in question is their effort to amend the International Organisation for Standardisation (ISO) definition for auto-disable (AD) syringes to gain strategic competitive advantage in the market. According to domestic industry representatives, the proposed revision of ISO 7886-3 Standard of AD syringes for fixed-dose immunisation will favour a few multinational corporations and put manufacturers from India and other developing countries in jeopardy.

"The ISO is a private organisation. But the government and the industry should keep an eye on developments there. Instead of copying the ISO, we need to use standards to protect our industry in the same way developed countries are doing," KM Gopakumar, a senior researcher with Third World Network (TWN) told Pharmabiz. The move to formulate the Indian National Strategy for Standards is a welcome step, he added. The draft of the strategy is finalised and the commerce ministry is putting the finishing touches to it.

In the case of AD syringe, a four-member expert sub-group of ISO Working Group 11 has decided to change its definition. Syringes with a mechanism to activate AD function at the beginning of injection were termed AD and this change was incorporated in the initial Committee Draft of the standard. By this change, over 66 per cent of the existing WHO Performance, Quality and Safety (PQS) designs could be disqualified despite being auto-disable. "Two of these so-called expert members were from Becton Dickinson and Terumo. Both companies are producing the defined type of AD syringes," an ISO committee member said on condition of anonymity.

"But many developing countries do not respond to ISO-circulated draft standards and if they don't have appointed subject experts who can defend their national interests then they lose their voting status and become observers. Bangladesh and Kenya became non-voting observers this way," the panel member pointed out.

The voting on AD syringes definition went awry as two countries that wished to vote against the move - Kenya and Bangladesh -- got electronically registered incorrectly and the ISO system did not allow a correction as disapproval. Objection votes of other countries - the UK, India and Indonesia -- were inadequate to disallow the change from going forward.

"The government should urge the WHO to intervene in ISO standard making processes assertively. The AD syringes issue shows that the government and the Bureau of Indian Standards need a mechanism to step in to support its manufacturers who may not have the expertise in standard making process," Forum Coordinator of Association of Indian Medical Device Industry (AiMeD) Rajiv Nath pointed out.

"The whole system is designed to enable professionals and MNC experts to create a system in their favour. Either the developing countries are not represented on these committees or they are unaware of what is going on as the reports and on-going work are not posted on ISO website. They are accessible only to committee members and the learning curve for first time attendee of meeting and process is steep," another industry representative opined.

MNCs have offices all over the world and use them to get votes in their favour through these countries. "It's been a challenge for us to educate similarly impacted MSME manufacturers in countries like Vietnam, Bangladesh, Nigeria and Kenya about the effect on their businesses and seek nominations to the ISO Working Group via their country's respective standard-making institutes," head of a domestic medical device manufacturing company who attended many ISO meetings said.

"English language is another challenge to communicate effectively at these meetings as representatives from China, Vietnam and South American nations get handicapped. The representatives of MSMEs are overwhelmed and tongue-tied during technical discussions with experts from the US FDA and MNCs as we are not backed by experts from BIS to guide us or CDSCO to support us," he added.

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