Pharma industry considering 'ethics inspectors' to ensure better compliance

Sohini Das | Mumbai Last Updated at January 20, 2020 21:09 IST

Pharma players to meet DoP to discuss suggestions around implementing ethical marketing practices code.

As debate over alleged 'unethical' marketing practices by India's drug firms rages on, the industry has sought to bring in transparency into the system by laying down strict rules to be followed by companies.

The Indian Pharmaceutical Alliance (IPA) is of the opinion that laws should be in place to regulate marketing practices, and non-compliance should be penalised. The proposal to be taken up for discussion with the government soon suggests something along the lines of having 'ethics inspectors' to ensure better compliance.

The Department of Pharmaceuticals (DoP) had drafted uniform code for pharmaceutical marketing practices (UCPMP), which is voluntarily followed by drug firms since 2015. The code is not mandatory yet and there is no legislation that lays down guidelines for marketing practices adopted by drug firms with health care providers.

Sudarshan Jain, secretary general of the IPA, which represents big pharma firms in India, said the association cannot monitor or control each and every pharmaceutical firm in the country. "The DoP should set up a process to monitor the implementation of the code and make it mandatory on the lines of the US system. Those who violate (any pharma company found guilty of violation of the code) should be penalised. This should be clearly laid down in the process," said Jain.

He added there should be a proper process of appeal. If any firm is found guilty, it should be charged a penalty. All this should be built into the code itself, felt the IPA. The IPA would soon take it up with the government. It said the DoP should have a mechanism whereby officers would monitor adherence to the code. If a complaint is brought before the DoP, it should be investigated and proper action taken, felt the industry body. However, this is possible only when the code is made mandatory and a legislation is passed to this effect.

A senior government official said it is possible to legalise the UCPMP and make provisions for penalty in the Drugs and Cosmetics Act.

The DoP had called a meeting last month seeking recommendations from the industry on what should be part of the code. Another meeting with the industry is likely in a month's time.

The industry thinks that continuous education of doctors is required and the pharma industry plays a significant role here. The code should allow drug firms to engage or sponsor scientific education of doctors (especially around new drugs).

"A proper process should be laid down around this and conveyed to every pharma company. While the education of doctors should be allowed, there should be hospitality offered (for example, taking them to a resort, sponsoring trips with families, etc)," said a pharma industry source.

The chairman of a leading drug firm in the country felt that unlike the world of advertising, which has a self-regulatory body (The Advertising Standards Council of India), it is not practical to have a self-regulatory body in the pharma industry. "The US has something called the Physician Payments Sunshine Act, which requires drug firms to disclose any payments made or transfers of any significant value to health care professionals. Such a thing needs to be adopted in India. The government can take punitive action against those who do not comply," he said.

Companies should make such disclosures in their books, and the documents should be available for scrutiny by the DoP-appointed officers in case of any complaints against the companies, the industry said. This should be applicable to both listed and unlisted pharma firms.

Moreover, the industry also felt that proper implementation of the code is possible only when the UCPMP is in sync with the Medical Council of India's code of ethics. Meanwhile, the IPA has also sought some simplification in the bureaucratic process, like drug firms are required to maintain a record of the free medicine samples given to doctors.

"Nobody gives samples of an expensive cancer drug. Samples given are for simple antacids, or antibiotics, with no real significant value. It is difficult to maintain records of all such free samples given to physicians," said Jain. He added that the industry is providing affordable medicines to millions and should not be seen in a bad light due to rumours, perceptions or aberrations.