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Pharma regulators concerned over adverse drug reactions

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In the next 10 years the number of pharma manufacturing units will rise by six times from current level of 12,000 units and it becomes all the more important for India to see that while its drugs manufacturing and their exports registered a manifold increase with no suspicion in their content and quality.

This was stated by the secretary, department of pharmaceuticals, ministry of chemicals and fertilizers, Dr V K Subburaj while inaugurating a Conference on 'Pharmacology: R&D for Minimizing ADRs and Role of Pharmacists' under aegis of PHD Chamber of Commerce and Industry on September 23 at New Delhi.

Mr Subbaraj pointed out that ADRs (Adverse Drug Reactions) happen due to multiple reasons as variety of stakeholders are involved in drugs administration and therefore, the time has come when India is required to put in a place a sort of regulatory mechanism that can keep an eye to curb the menace of rising ADRs as the tendency that prevails currently is to hush up such cases.

"America for example, set out to address this issue way back in 1962, consequently little number of cases of ADRs are reported there though India also awake to this fact in 1982, we have achieved little progress to contain ADRs. This is because it has not been able to create an effective mechanism to address the issue", said Mr Subburaj.

According to him, no definite and effective statistics and estimates are available as to how many cases of ADRs happen each year while in America such statistics are accurate and the system in place, India therefore, needs to emulate such a country to address the issue of ADRs with an effective monitoring system in place.

Later on speaking on the occasion Drug Controller General of India Dr G N Singh concurred that ADRs is the serious issue and the authorities concerned are in constant touch and consultation process with functionaries of WHO so that protracted deliberations are concluded in which representatives 100 emerging economies assemble here and find out ways and means to evolve a regulatory mechanism to contain the menace of ADRs.

On the suggestion by the expert panelists that the pharmacists be allowed to prescribe medicines for ailments of general nature, the DCGI said that the government will view it with an open mind. He also stressed on the suggestion saying Pharm D graduate should be employed at district or sub-taluka level PHCs.

He has also given a suggestion to classify the drugs into three categories i.e. the drugs (OTC) which consumer can take directly from medical store, few limited drugs which could be prescribed / suggested by pharmacists and the specialty drugs prescribed by medical doctors. This will also improve the access of healthcare services especially in areas where there is shortage of doctors while the pharmacists are available.

NABH guidelines will also now look at including the role of pharmacists for the accreditation said CEO, NABH Dr K K Kalra. Among other who were present on the occasion comprised chairman, health committee, PHD Chamber Mr Nishant V Berlia and its secretary general Mr Saurabh Sanyal.