Pharmexcil wants Centre to draft a policy for orphan drugs to promote its exports

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To tap the huge potential of orphan drugs, the Pharmaceuticals Export Promotion Council of India (Pharmexcil) wants the government to focus on setting up a strong regulatory framework to encourage its growth within the country. With an emphasis on this, the Council has called upon industry think tanks and experts to come forward with their suggestions, so that they can be submitted to the policy makers.

This move comes in the wake of lack of any definite policy guidelines within the country to regulate the orphan drugs market, affecting its growth prospects. This they feel is in spite of the huge untapped market opportunity it presents, not only in the domestic but also in the overseas market.

Orphan drug is a pharmaceutical agent that is used to treat a rare medical condition like glioblastoma multiforme, nocardiosis, tourette syndrome, etc. While countries like US, Europe, Japan, and Australia has already laid down legal framework for combating rare diseases, India is yet to take any step in that direction. According to Dr P V Appaji, director general, Pharmexcil, there is a need to encourage research and development initiatives for such drugs as surprisingly scores of patients are suffering from the so called orphan diseases.

He stressed, “Absence of orphan drug legislations in India is creating a lot of challenges to the manufacturers of orphan drugs. Thus through this initiative we want to ensure that all the expert opinions and recommendations are duly submitted to the government so that they can take requisite steps to prepare guidelines that will help set conducive environment for the development of drugs for rare diseases also known as orphan drugs.”

The Council strongly feels that in the light of the current healthcare needs there is an urgent need for the government to encourage domestic manufacturers to get engaged in research for orphan drugs by putting some regulatory guidelines in place. Not only that they should also extend financial support, regulatory concessions and promote exports of the same.