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Need for orphan drug provisions in India

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An orphan drug is a pharmaceutical agent that has been developed specifically to treat a rare medical condition. India Currently has no regulations for orphan drug manufacturing or selling. It is estimated that 72,611,605 people are affected by rare diseases in India (2011). About 6000 to 8000 rare diseases, mostly genetic in nature have been identified. Recent news about orphan diseases in India was tracked and the data was compiled. No specific primary medication is available for orphan disease in India. However, secondary medications are being used for preventive treatment of these diseases. A group of pharmacologists requested the Indian government to enact the Orphan Drug Act in India at a conference held by the Indian Drug Manufacturers Association in 2001. However, this was a dead end as no such provisions have been initiated by the government till date. It is necessary on the part of the Indian government and regulatory bodies to implement such provisions and bring about a whirlwind of change by enacting provisions related to orphan drugs.

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