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Analysis of patient access to orphan/rare drugs in Pakistan

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Background: Orphan/rare diseases are chronic, serious, and life-threatening conditions that have a low prevalence and require complex care. Worldwide, as estimation one in 15 people are affected by rare diseases. This study aims to analyze the accessibility, reimbursement status, licensed status of drugs and __ (ATC) codes of drugs that the European Medicines Agency (EMA) in Pakistan considers to be "orphan" pharmaceuticals.

Methods: The drugs included in this analysis were obtained from the list of orphan drugs published by the EMA. Orphan drugs' accessibility and licensing status in Pakistan were obtained from the list of FDA orphan drugs. Descriptive analysis was applied to determine the accessibility status of orphan drugs identified by the EMA in Pakistan.

Results: Based on the EMA, 105 pharmaceuticals were approved with "orphan drug" status except for drugs that have lost orphan drug status, decommissioned in the European Union and withdrawn from the European Community Register by January 2020. Of the 105 rare drugs on the EMA list, 84 were inaccessible in Pakistan. Of the 21 available drugs, 1 (0.87%) were licensed and 20 (99%) were unlicensed in Pakistan. Among 1 (0.87%) of licensed products and 20 (99%) of unlicensed products were not covered by reimbursement. When orphan drugs' ATC codes were examined, the most common ATC group was found to be "L—Antineoplastic and Immunomodulatory" agents.

Conclusion: An orphan drug incentive policy is very important to ensure early access to the drugs used to treat orphan/rare diseases. Considering the capacity and prices for orphan drugs in Pakistan, it can be said that almost every patient with orphan/rare diseases have difficulty in their treatment. It is obvious that such a policy must prepare for the regulation of orphan drugs in Pakistan.

Keywords: Rare disease drug, Orphan drug, Orphan drug market

Biography

Rizwan Arshad is a young public health researcher having 13 years of experience on accessibility of medicines (ATM) primarily hard to hard to find medicines including rare and orphan drugs for the vulnerable patients in Pakistan. Currently he is working on the model development of one window services model (OWSM) for the accessibility of cancer immunotherapies and orphan/rare drugs on named patient basis. It is his research model and core interest area as well. He has been associated with many organizations as a consultant for the alignment of health services along with regulatory authorities and identification of gaps in health for the communities and provides the solutions thereof. He is also responsible for making an outreach to peripheries within the country for the accessibility of quality drugs to the community people.

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