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Medicine Withdrawal and Recall: Needs Proper Evaluation

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Currently, withdrawal and recall of medicines become a hot topic of discussion. This issue does not follow a uniform pattern all over the world.

Few medicines continue to remain in the market despite reported adverse effects. This is understandable because: [1]

• They may be the only available options for a few sets of patients e.g. felbamate (anti-epileptic)

• Drug remains in the market until better options are available in terms of safety and efficacy e.g. terfenadine approved in 1985 was found to cause cardiac arrhythmias but it continued to be in the market till the arrival of newer analogue fexofenadine in 1997.

• Withdrawal may also become the last option to choose if all other risk management techniques fail as was observed in the case of heartburn treatment with cisapride.

While comparing the drug withdrawal and availability pattern among different countries, we can see that some drugs withdrawn in one country continue to be used at other places. This may be due to valid reasons like difference in disease pattern, prescribing practice, genetics, diet; drug manufacturing process used which influence pharmaceutical quality and composition, dose and availability. But sometimes strategies of pharmaceutical companies and role of regularized authorities make this issue controversial e.g.

• Aprotinine is withdrawn in UK and Europe, subjected to restricted use in USA, Canada, Australia and Singapore but is freely available in India [1].

• Tegaserone is withdrawn in USA but is available in India [1].

• Nefazedone is withdrawn in Canada and Singapore but is in use in Europe and USA along with safety alert [1].

• Nimesulide, which is a Non-Steroidal Anti-Inflammatory Drug (NSAID), was already banned in over 170 countries worldwide including US, UK, Canada, Sweden, Denmark, Japan, Australia and New Zealand long back because of its serious side effects including liver toxicity. It was continued to be extensively prescribed to adult and pediatric patients in India but now banned since January 2011 [2].

Similarly, recall of medicine has also become controversial these days. The most appropriate example is of buclizine which is again back in market as an appetite stimulant. It is really a controversial topic to prescribe an appetite stimulant to paediatric patients [3]. The possible mechanism behind use of buclizine for this purpose is its property to cause anoxia which results in increased peripheral utilization of glucose leading to increased appetite and weight gain. But this tissue anoxia leads to increased anaerobic glycolysis by the same mechanism as that of phenformin which causes lactic acidosis and is the reason for its withdrawal. Buclizine is a highly lipophilic compound and crosses blood brain barrier in large amount. So, prolonged use of it as an appetite stimulant can create increased drowsiness. These adverse effects are not mentioned in the promotional literature issued by the company either as precaution or as alert for prescribers [4].

Another important compound in the list is vanadium compound which shows insulin-like effects in vivo and in vitro. Majority of the studies examining vanadium effectiveness are animal studies; only a few clinical trials have been done which address the issue of safety at high doses. For the same reason, despite of pleiotropic actions, vanadium is not much recommended for any disease or condition. Now there is reconsideration of the compound for use in diabetes mellitus which requires further exploration [5].

In addition, there are so many older compounds which were banned previously but are back again for either same or different indication. Sometimes a drug is known to provide significant benefits to a substantial portion of the population but a relatively infrequent occurrence of harm may give rise to demands for the drug to be restricted in use or withdrawn completely. Despite stringent regulatory norms, harmful drugs pave their way into the market, compromising public health. Assessment of risks and benefits should be done without any bias, as the generated evidence forms the basis of the next decisive action. Continuous medicine safety monitoring through pharmacovigilance is essential to safeguard against the adverse effects of medicines.

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