Advances in Pharmacoepidemiology & Drug Safety

Patil, Adv Pharmacoepidemiol Drug Saf 2015, 4:4
DOI: 10.4172/2167-1052.1000e131

Editorial Open Access

Drug Safety and Indian Pharmacist

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Introduction

Harmful effects of drugs and medicines can be minimized in the drug consumers through effective functioning of pharmacovigilance team in the health care system to assure the safety of medicines. Majority of drugs have been banned since 3-5 years in other countries but are still available for sale in India. The manufacturing and marketing of many single drugs as well as fixed dose combinations has been also banned in India. Adverse drug reactions (ADR) of such drugs which are still available in market have not been reported. Safety issues related cardiovascular events and liver damage are main reason to withdraw such category of drugs. Due to lack of standard practice of its own in India made it difficult to concentrate on drug safety issues. To make it more effective there is an urgent need of establishing a policy for multidisciplinary approach towards drug safety that can be effectively implemented throughout the entire duration spanning from drug discovery to usage by consumers. Drug banning by regulatory authority or voluntarily withdrawal is mainly due to the adverse events pose a risk greater than the benefit provided by the drug. If a commination formulation causes adverse effect, then the combination product is banned and not the individual drug. Many single drugs or used in combination with other drugs are discontinued from being produced and provided in the Indian market.

Banned Drug Monitoring Committee

Many of over the counter (OTC) drugs are available in Indian markets in same brand name which are banned in most of the countries. OTC drugs are those which are available without prescription in the medical shops, so the ley man is ignorant about the serious side effects. This is a serious issue that Indian regulatory authority is concerned about [1]. Some products such as human placental extract are mandatorily banned by Drugs Controller General of India (DCGI) but are still available in the market. This may be mainly due to delay in judiciary process and undue advantages are being taken by the manufacturers for unethical distribution and availability of banned drug. Hence, it led to lie in the insufficient data about ADR and its reporting.

Indian regulatory authority had a provision to constitute a sub-committee to monitor the individual circulation of banned drugs in the country. The Drug Technical Advisory Board (DTAB) under the Drugs and Cosmetics Act (D and C Act) can constitute sub-committee comprising subject experts. The safety and efficacy of drug is ascertained prior to marketing in accordance with Schedule Y of D and C Act and is continuously examined even after drug approval based on the information collected from pharmacovigilance, post-marketing surveillance and information reported from other countries. The sub-committee consisting of experts on the subject is authorized to examine the information received from the sources mentioned above and take a final decision about prohibition of its manufacturing and marketing or to restrict its use and accordingly recommend the Government to make suitable amendments under Section 26 A of the D and C Act which empowers the Central Government to prohibit the manufacturing and marketing of such drug [2].

Drug Safety and Indian Pharmacist

Each and every country has its own strategies and mechanisms to ensure the drug safety in public health care system. The responsibility of public health and patient safety in United Kingdom is with department of health, and medicines and health care product regulatory agency (MHRA) is an executive agency acts on behalf. This agency is authorized to ensure the safety, quality and efficacy of medicines as well as healthcare products. Similarly, the United States, Food and Drug Administration (FDA) are the Federal public health agency that has regulatory responsibility for ensuring the safety of all marketed medical products, including pharmaceuticals and biologicals. In spite of all these regulatory measures, professional competency and updating ever-changing developments among the health care professionals especially pharmacists is need of the present hour in the Indian health care perspective. To achieve maximum drug safety in public health care role of pharmacist very much important. Despite of need for multifaceted approach which is essential in regulation of drug safety in Indian market, it is very much essential to educate the pharmacist in clinical issues and establish the transparency in regulation procedures of drug safety which is apparent presently. The lack of stringent control on every pharmacy with respect to mandatory presence of pharmacist at all the times during transaction period causing many problems in drug safety aspects. Hence, authorities of drugs control mechanism of every state should strictly abide by the D and C Act 1940. Pharmacist involved in health care team must be able to educate assistant pharmacists as well as patients visiting the pharmacy in many aspects such as patient counseling, good label practice, and providing information about ADRs in the form of handouts, leaflets and posters and at last advice to report any ADRs to pharmacists or other healthcare professionals. Apart from this, more essentially required for our health care system is to establish and implement the mandatory Continued Pharmacy Education (CPE) programs pertaining to clinical pharmacy issues for pharmacists. So that pharmacist can update and refresh his knowledge about recent advancements and changes in pharmaceutical sciences. CPE programs also help in educating pharmacists about how to report and whom to report ADRs in their practice. It is a duty of central government to educate the ley public about black health care issues through various media. Pharmacists and nursing staff are an integral part of improving awareness about pharmacovigilance in India. Their efforts contribute to the ADRs reports and smooth maintenance of up-to-date documentation hence they should be given due recognition and considered an integral part CEP [3].

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Received June 18, 2015; **Accepted** June 23, 2015; **Published** June 25, 2015

Citation: Patil JS (2015) Drug Safety and Indian Pharmacist. Adv Pharmacoepidemiol Drug Saf 4: e131. doi:10.4172/2167-1052.1000e131

Conclusion

Over work burden on physicians, pharmacists and nursing staff, causes ignorance in noticing many of ADRs occurring in practice. This is mainly because of poor pharmacovigilance system existing in India. CPE programs refresh and update our current generation of pharmacists and their active participation in health care issues, we can hope to provide a better health service to public and ensure drug safety.

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