Pharmacovigilance: Is it possible if bannable medicines are available over the counter?

During a group exercise concluded recently in the International training course on promoting rational medicine use in the community, almost all the participants ranked the pharmaceutical industry followed by the national Governments, international health organizations, NGOs, health professionals and consumers, in that order for existing unhealthy pharmaceutical policy.[1]

In the recent past critical opinions have been aired about the sale of many drugs from India that have been banned in other countries. World over Nimesulide has been withdrawn, but continues to be sold in India.[2] Another drug that has been voluntarily withdrawn recently by the manufacturer (Merck) from the world market was Vioxx® (Rofecoxib).[3] The company’s decision, which became effective from September 2004, was based on the three-year data from a prospective, randomized, placebo-controlled clinical trial. However, no alert has been issued in India even after the media focused attention, and pharmaceutical companies as usual, seem to be uninterested in voluntary recall.[4]

It is beyond the rational understanding why we in India continuously refuse to learn from the bad experiences of others, despite the ready availability of knowledge. We prefer to conveniently shut our senses because that is most comfortable and in the process let the bannable medicines continue to thrive and prosper.

Now in public eye is phenylpropanolamine (PPA), a synthetic, sympathomimetic amine. It is almost ubiquitous in over-the-counter (OTC) cough/cold remedies and appetite suppressants. Reports link the use of these products to stroke. A survey conducted in the United States between 1994 and 1999 showed that women using PPA as appetite suppressant had higher incidence. The PPA-induced intraventricular hemorrhage[5] has also been reported from India.[6] Rightfully, the PPA has been banned in many developed countries but continues to be a common constituent of many formulations in India. Some companies have switched PPA but continue to retain its old brand name.[7] The Family Welfare and Health Secretary, Government of India, has accepted that it has been alerted about PPA and are technically evaluating it.[8]

In 2000, the US FDA issued a Public Health Advisory informing that it was taking steps to remove PPA from all drug products and has requested that all drug companies discontinue marketing products containing PPA. It warned of stroke risk associated with the PPA, and these drugs were removed from store shelves.[9] In June 2001, Health Canada issued health advisory regarding PPA advising its citizens that after assessment of the safety of PPA, drug products containing PPA were being withdrawn from the market while we here in India still feel the need to evaluate it in 2005!

This is yet another case of precious time-being lost in banning the problem-containing medicine, unduly exposing the user clientele to its adverse effects (ADRs) and health hazards. It is beyond the comprehension why such medicines, which have been withdrawn by the developed countries, cannot be immediately banned worldwide? The media continues to publish lists of banned medicines available in India.[9] For what reasons do we wait? Is our “technical evaluation” any way better than the developed world’s? If it is so, then how many medicines have been banned in India for the first time in the world? Or is our population anyway different in not suffering from ADRs reported globally? In some countries ADRs rank among the top 10 leading causes of mortality. It is also possible that since ADR monitoring and reporting are almost nonexistent, mortality due to ADRs are getting passed on to some other head!

‘WHO defines pharmacovigilance as the science and activities relating to the detection, assessment, understanding and prevention of ADRs or any other, medicine-related problem.’[10] What can we expect from pharmacovigilance if banned medicines continue to be sold over the counters?

V. Thawani¹, S. Sharma², K. Gharpure³
¹Department of Pharmacology, Government Medical College, Nagpur, ²Department of Pharmacology, Indira Gandhi Government Medical College, Nagpur, India
E-mail: vijaythawani@rediffmail.com

References