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The Network's NEWSLETTER

Association for Rational Use of Medication in Pakistan

No short cuts for policy making

The caretaker government's 90 days in the office are marked by a show of hyper-activity. The haste and hurry with which it took up every task may be good in many aspects but is harmful and detrimental in many regards as well. Policy making and that too related to health is no joke. It does not just involve some bureaucratic maneuvers. It is not that the Minister utters some magic words like 'open sesame' and here it is the National Drug Policy.

A public policy document has to be a product of a process of debate and discussion involving all the stake-holders of the pharmaceutical sector. The policy could only be successfully implemented if the varied and contrasting opinions of different stake-holders have been duly considered and used to evolve a position of optimal acceptance. But the caretaker set up did not bother to consult any stake-holder, perhaps because the policy is not meant to be implemented. It is a piece of paper that will enable the minister to lay a claim that he accomplished in 90 days what others could not in 50 years.

The document of the National Drug Policy is abysmally poor in the quality of its content, language and presentation. It claims to do things which are opposite to what other departments of the government are dying to achieve. Its contents are self contradictory and even incomprehensible. Its vision is myopic and conventional and the jargon is out of date. It is in no way a document that could help us survive the new corporate onslaught in the name of globalization. Through this document, the Ministry wants its critiques to start believing that it is busy doing a lot.

The Network hopes that the new government which enjoys overwhelming majority in the parliament will kick start the process of drug policy making afresh involving all the stake-holders.

The Network s mission is to promote rational use of medication and essential drugs concept in Pakistan in order to optimize the usefulness of drugs and help bring equity in their access.

DrugNews

FDA to disapprove Seldane (Teldane)

The Food and Drug Administration of USA (FDA) has announced its intention to withdraw the approval of Seldane (terfenadine), Seldane D (terfenadine and pseudoephedrine) and generic versions of the prescription antihistamine on 12 January 1997. FDA has determined that drugs containing terfenadine are no longer shown to be safe because fexofenadine is now available.

FDA recently approved a brand of fexofenadine, the primary active derivative of terfenadine produced in the body when terfenadine is taken. Fexofenadine provides nearly all of terfenadine's beneficial effects but does not appear to cause a potentially fatal heart condition when taken with some other commonly prescribed medications.

Introduced in 1985, terfenadine was marketed as the first prescription antihistamine to relieve the symptoms of allergic rhinitis without causing drowsiness. Following approval, FDA received reports of serious and sometimes fatal cardiac arrhythmias associated with terfenadine when it was taken with some other medications or by patients with liver disease. These other drugs, such as erythromycin (an antibiotic and ketoconozole (an antifungal drug), can cause terfenadine build up in the blood and result in serious cardiac side effects.

Prior to the approval of fexofenadine, the agency considered the benefits of terfenadine to outweigh its risks despite its known serious cardiac adverse effects when used inappropriately. Now that fexofenadine is available and provides the therapeutic benefits of terfenadine without the associated serious cardiac risks, terfenadine's benefits are no longer considered to outweigh its risks.

In view of these developments, FDA has determined that terfanadine-containing products should be removed from the market. The 12 January Notice of Opportunity for Hearing from the FDA gives the manufacturers 30 days to request a hearing to show why approval of the registration (New Drug Applications or ANDA for the generic version) should not be withdrawn.

In the meantime, FDA is advising patients currently taking Seldane, Seldane-D and generic terfenadine products to talk to their doctor about switching to alternative medications.

Raw materials: From India with ...

The caretaker government has decided to allow the import of raw materials for pharmaceutical industry from India. This is being done to help bring down the prices of medicines in Pakistan.

According to daily *Dawn* the authorities are of the view that Indian chemical and pharmaceutical industry has developed tremendously in the recent past and it can provide the raw materials at very competitive price. Currently, the raw materials imports from India and Israel are banned. Official sources told *Dawn* that the import of finished goods (medicines), however, would not be allowed from India.

The Network welcomes any move to lower the high drug prices in Pakistan but thinks that this particular move may not be very helpful in this regard. The Network has this considered opinion that it is not the price of raw material that has made medicines in Pakistan costlier than in India but the absence of an effective price control. The raw material from China, Brazil or Italy is most of the times as inexpensive as that available from India but the manufacturers either fraudulently show it to be much higher (called transfer pricing) or simply raise their profit margin to thousands of percents. The prices can only be brought down by checking the practice of transfer pricing and setting a formula for fixing the prices.

The drug price situation in Pakistan is worsening because a cartel of multinational companies has monopolized the market. Their monopoly is getting stronger by the mega mergers and take overs. The local companies are either too weak to offer any competition or are dependent on multinationals for contracts or business. The Network considers this situation of no-competition as the major cause of high prices and only the import of raw materials from India would not help bring competition into our market.