Editorial Spurious Medicines – A PIC Disaster

Dr. Azhar Masud Bhatti
Addl. Director Health Services, EPI Punjab, Lahore
&
Editor in Chief

The World Health Organization (WHO) claims that between January 1999 and October 2000 alone, 46 confidential reports relating to such drugs were received by it from 20 countries. While about 60 percent of these reports came to the WHO from developing countries, the remaining 40 percent were reported by developed countries. It is pertinent to note that at present, out of the 191 WHO member states, about 20 percent are known to have well developed drug regulation, about 50 percent implement these regulations at varying levels of development and operational capacity and the remaining 30 percent either have no drug laws in place or have very limited capacity that hardly functions. A research conducted by The News International, by taking into account the January 2010 report of the WHO and the April 5, 2008 edition of London's Daily Telegraph newspaper, reveals that counterfeiting is greatest in regions where regulatory and enforcement systems for medicines are weakest. The January 2010 report of the WHO reads: "In most industrialized countries with effective regulatory systems and market control (i.e. Australia, Canada, Japan, New Zealand, most of the European Union and the United States of America). Incidence of SFFC medicines is extremely low less than one percent of market value according to the estimates of the countries concerned. But in many African countries, and in parts of Asia, Latin America and countries in transition, a much higher percentage of the medicines on sale may be SFFC." The April 5, 2008 edition of London's Daily Telegraph states: "The multi-billion-pound global trade in bogus medicines is responsible for an estimated half a million deaths a year. The WHO estimates that 200,000 of the one million malaria deaths a year would be prevented if all the drugs were genuine.

Punjab government acted very promptly and within few days the whole investigation has been completed. Tests conducted by a British Regulatory Agency has now established the cause of the death of at least 150 people. They had been prescribed a contaminated medication supplied by Efroze Chemical Industries of Karachi. An Antidote to the contaminated drug has been quickly identified, is fortunately easily available and has already been administered to many of those currently suffering. The chemical causing the deaths and illness is an anti-malarial called Pyrimethamine which adversely affects bone marrow and, if taken in sufficient quantity, causes death. It was present in Isotab, the drug prescribed to patients of PIC in quantities upto 14 times the recommended weekly dose, a level of contamination that will inevitably have serious consequences. The samples of the drug were sent to laboratories in Karachi and Lahore but they failed to detect the contaminant, which means that even if the drug had been tested before it was distributed, the problem would have been undetected. Our testing facilities are therefore far below the required standards as acknowledged by Chief Minister Punjab Shahbaz Sharif who promised an upgrade to international standards in the near future.

This issue relates to the failure of quality control by the manufacturer and the drugs regulatory body at federal level. Ultimate responsibility lies with the manufacturer, and the CEO of Efroze speaking on a private TV talked of a theft of Pyrimethamine from the company last September and the possibility of a conspiracy, against the company. This is palpable nonsense. It is for the manufacturer to batch test their products before they leave the factory. They are producing a drug that is currently prescribed by doctors to patients whose lives may depend on their medications. There is no greater duty of care than to ensure that a safe product leaves the manufacturer. It is also worth nothing that it is probably unfair in this instance to penalize the doctors who did the prescribing. They would have been unaware that they were giving out dangerous medication, and the contamination is not something that would be visible to the naked eye. There may well be issues around the checking of medicines purchased by individual hospitals, but it is unrealistic to expect every doctor to check the veracity of every drug he or she prescribes. Let us hope that lessons are learned by all concerned in this most avoidable of tragedies.

The problem of spurious/falsely labeled/ falsified/ counterfeit (SFFC) medicines was first addressed at international level in 1986 at a conference held in Nairobi, the multi-billion-dollar global trade in bogus drugs is still responsible for over half a million deaths every year.

This chemical produce immediate bone marrow suppression which resulted in immediate drop in platelets and the white cell counts which led to the death of these people. Ironically the action of this drug is similar to Dengue Virus which also attacks the platelets. Although both conditions are entirely separate, the eventual effect on the patient is similar, which is quite amazing. Both conditions created challenges for the Punjab government one after the other. The generic name of this medicine is Isosorbide 5-Mononitrate.

It has been found that there had been other adulteration in the medicine. It has been traced that 50mg of Pyrimethamine has been contaminated in each tablet. Pyrimethamine is used in the treatment of complicated malaria.

The affected patients reportedly have been taking 20mg of Isotab twice a day, alongwith other medications, which includes Aspirin, which also acts to dilute the blood.

Drugs must be taken in the recommended dosage otherwise these can be poison. A strict quality control must be in place.

In Britain, a book is published regularly which is called British National Formularly and its edition 63 is likely to be out in the market by March 2012. This essential reference provides up-to-date practical guidance in prescribing, dispensing and administering medicine. The BNF evaluates clinical evidence from diverse sources with information validated by a network of clinical experts and published under the authority of a Joint Formulary Committee. The BNF reflects current best practice as well as legal and professional guidelines relating to the uses of the medicines. This book is consulted by doctors on a regular basis before prescribing any medicine.

All the doctors practicing in the UK benefit from BNF. They take advice for indication, contra indications, side effects and recommended dosage of the medication.

No doctor can remember all the medicines and their names available in the market, nor can they remember the recommended dose. Our colleagues practicing in Pakistan do not have such facilities available. This booklet also contains a list of the medications which are approved and considered safe to be prescribed. Although this booklet contains all the information, still the medicine mentioned in the books must be prescribed by the doctors only. Without this type of facility available on top of the table it is not safe to practice.

The new Medicine Act was brought in by introducing a number of other legal provisions for the control of medicine. It was an enabling Act providing for a system of licensing, affecting manufacturers, sale, supply and importation of medicine products into the UK. It became unlawful to engage in these activities except in accordance with the appropriate Licence certified or exceptions. The UK was the only country to control medicine in this fashion. Indeed medicine control was an early area of activity in the European Economic Community. The first time basic European Economic Community directive to control medicine was introduced in 1965. Safety, quality and efficacy are the only criterion on which legislation to control human medicines is founded. It is the responsibility of the Medicine and Healthcare Regularity Authority (MHRA) and the expert advising bodies, set up by the Medicines Act to ensure that this sometimes difficult balance between safety and effectiveness was achieved. MHRA experts assess all applications for new medicines to ensure that they meet the required standard.

The recent disaster in Punjab has attracted media attention and a blame game started which is not beneficial to anyone. However, the sacrifices of these few lives can lead to a proper regulation and can save thousands of lives in the future.

Sales of medicines without prescription should be banned. It is a collective effort which needs to be done by all the provinces and the centre to put a foundation stone for safety of patients for the future. It is a part of evolution and every country has to go through these times.

History may tell of other incidences like that which happened in the Punjab recently, but it is more important to stop it from recurring.

If no such effort is made at this time, next time such a catastrophe may be in another province and you will find no Punjab government to blame for it. There is need to strengthen the Drugs Regularity Authority and also need to improve and modernized Drug Testing Laboratories at Federal and Provincial level.