EDITORIAL

PUBLIC CONCERNS REGARDING EFFICACY AND SAFETY OF MEDICINES

A recent debate in one African country regarding cough medicines brought into the fore a simmering public concern regarding efficacy and safety of medicines. The debate was prompted by a retrospective study conducted at Pennsylvania State University which indicated that cough mixtures for children are relatively ineffective and possibly harmful. This information was widely disseminated by a consumer pressure group and published in *Consumer Reports*. There was an attempt, albeit inadvertently, to distort information which has been in the public domain for several years. Use of cough mixtures generally and specifically in children below six years of age is controversial and there is no consensus among health professionals. This is partly attributed to lack of suitable laboratory models to study cough, which is a symptom rather than a disease. It is, however, generally accepted that use of cough suppressants containing dextromethorphan, codeine and pholcodine is undesirable in this age group. There is extensive published information on this subject, particularly on the internet.

One issue which characterized this free for all debate is the right of the public to be informed about the efficacy and safety of medicines. A lay person cannot understand why national governments would allow the use of medicines with no proven benefits and possible harmful effects for so long. To compound the issue, it was later confirmed that the Ministry of Health in the country had discontinued use of cough mixtures in public hospitals more than 12 years ago. The official explanation that drugs in government hospitals are procured on the basis of VEN (Vital, Essential, Non-essential) and that cough mixtures which fall under the last category were discontinued as a cost cutting strategy was greeted with scepticism. The debate had degenerated into a free for all with politicians, herbalists, consumer pressure groups and health professionals competing for attention. The debate also provided a convenient platform for medical and pharmaceutical professional societies to try and outdo each other. One could only hope that a similar debate will spill over to other equally controversial medicines. It is not a secret that the use of certain classes of drugs is associated with significant morbidity and mortality. Among the drugs/classes of drugs worth of mention are the oral contraceptives, anticoagulants, steroidal anti-inflammatory drugs used in asthma and fluoroquinolones. Some of the published information on these drugs lacks scientific credibility but is readily available to the public through the internet. I shall limit my comments to fluoroquinolones to expound on this point.

There has been serious concern regarding the use of fluoroquinolones and more specifically gatifloxacin, levofloxacin and ciprofloxacin. Some of the side effects cited on the internet include the following: tendon and muscle pain, insomnia, anxiety, tinnitus, burning pain, heart problems, rashes, digestive disorders, visual disorders, hyperglycemia, depersonisation, paranoia, mental disorders, seizures, hallucinations, psychosis, panic attacks, depression, cognitive disfunction (brain fog), photosensitivty, taste perversions and abnormal dreams. Fluoroquinolones are among the most widely prescribed drugs and authoritative clinical data in professional medical journals indicate that they are both safe and effective. They are the drug of choice in typhoid and urinary tract infections and are widely used in many other systemic infections.

A class-action lawsuit was launched against Bristol-Myers Squibb alleging that the drug maker failed to warn patients of risks associated with the use of Tequin® (gatifloxacin). It is claimed that one of the plaintiffs, Alban Colon, a Canadian citizen aged 70 years, fell into a coma after taking the drug in March

2002. Bristol-Myers decided to withdraw the drug in 2008 because of the adverse publicity. Another consumer organization '*Public Citizens*' sued the US Food and Drug Administration (FDA) on January 3, 2008 regarding the adverse effects of Levaquin® (levofloxacin), one of the most widely prescibed fluoroquinolones in the market. The FDA had ignored the '*Public Citizens*' petition for almost 16 months but eventually relented and agreed to recommend a '*Black Box*' warning on the outer pack to the effect that fluoroquinolones may cause tendonitis. This is now a legal requirement for this class of drugs before they are registered in many countries. Currently, there are 15 liability cases filed regarding adverse drug reactions associated with Levaquin®. It is significant that the FDA, with access to extensive adverse drug reports and professional expertise, chose to ignore the consumer pressure group for 16 months.

The example of fluoroquinolones highlights the dilemma drug registration bodies encounter in reconciling public perception with scientific/professional reports regarding the efficacy and safety of medicines. At which point do we decide that the benefit/risk ratio of a particular drug is unacceptable? The debate regarding cough mixtures was fuelled by both electronic and print newsmedia as a business strategy to boost sales. Consumer organisations worldwide appeal to public emotions and suspicion of national governments. We are familiar with the theatrics adopted by environmental pressure groups in defense of '*mother earth*'. Unfortunately, appealing to public emotions when dealing with health matters can be counter-productive.

Editor-in-Chief