Editorial

'Rogue Medicines': The absolute pits of the world

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It is an almost virtual certainty, that this lexiconic phrase 'Rogue Medicines' is not a very well-known entity and is perhaps a figment of the imagination of this author. Yet for all that, it is used here to depict a most disgraceful aberration of sublime dishonour that has a telling impact on the practice of Western Medicine, not only in our little Sri Lanka but also in the whole wide world. It is meant to portray the questionable qualities of medicinal drugs.

In the widest possible general sense, medicines used to treat patients are therapeutic chemical compounds that are designed and used for the management of human diseases. They are the backbone of the practice of Western allopathic medicine as we know it, and have known it for centuries in the past. From time immemorial, the human race has worked at and looked forward to the refinement of existing therapeutic compounds as well as the emergence of newer medications that can alleviate human suffering. Such compounds have been scrupulously tested, efficacy and safety determined, their potency guaranteed and made available to needy patients in the best possible presentations for their usage. These concepts have always been the light at the end of a gloomy tunnel of disorders and diseases that afflict and affect the Homo sapiens.

However, some developments regarding several kinds of 'rogue medicines' are causing considerable concern worldwide at present. Two significant types of therapeutic compounds that can even endanger the lives of patients are currently being discussed all over the world. The first group of these rogue medicines are those that are labelled as Falsified Medicines. These are fake medicines that are designed to mimic real therapeutic compounds[1]. They are medical products that fail to meet necessary quality standards or specifications and are unregistered or unlicensed medical products that have not undergone all necessary evaluations or given approval by the National or Regional Regulatory Authority for the areas in which they are marketed or distributed. Many of these falsified medical products are ones that intentionally and dishonestly distort their identity, composition, or source. They have the potential to cause major problems ranging from life-threatening sensitivity reactions to faulty therapeutic activity and sometimes even total ineffectiveness for the diseases or disorders for which they are used. According to reports sent to the World Health Organisation (WHO) from 20 different countries, it has been postulated that most falsified drugs fall into one of the following three categories[2]:
(1) products containing no active ingredient: about 30%;
(2) products containing an incorrect quantity of the active ingredient: about 20%;
(3) products containing wrong contents: about 20%.

The second lot of the rogue medicines are Counterfeit Medicines which are those that do not comply with intellectual property rights or those that infringe trademark laws[3]. These are forms of forged drugs which could exhibit major therapeutic disadvantages. The World Health Organization (WHO) also defined counterfeit pharmaceutical products as those that are deliberately and fraudulently mislabelled concerning their identity and/or source[3]. Counterfeit products are hazardous to health as well as the economy, and this is a dilemma for almost all developed and developing countries around the world. Besides. they are a major cause of treatment failure, adverse events, mortality, economic strain, development of drug resistance, and loss of confidence in medicines and various health services.

Factors that increase a country's susceptibility to rogue medicines include healthcare infrastructure collapse, inadequate or improper regulatory procedures, and excessive costliness of essential medicines. According to a study in Nigeria, factors that contribute to the use of counterfeit medicines include illiteracy, ignorance, and weak law enforcement[4]. In that presentation, the main reasons for the prevalence of counterfeit medicine were the high cost of drugs and the greed of regulatory officials. This latter statement is a rather polite indictment of the degree of corruption in many countries. It is like an ever-present fiendish influence, overarching through the despicable spectre of rogue medicines. These very same contributory factors are more evident in developing countries like Sri Lanka than in more developed countries. A case in point is the recent fiasco in Sri Lanka where an unregistered brand of Intravenous Immunoglobulin preparation with dubious quality was purchased at an enormous cost with a waiver of registration (WOR) facility by the Ministry of Health. The said compound produced some major problems for those who used it to treat patients. Quite besides these undesirable effects, there were

no guarantees to say that the compound was free of blood-borne infective elements such as HIV and hepatitis C as immunoglobulins are manufactured from pooled human blood. Those patients who received this rogue drug would need long-term surveillance and repeated testing for HIV and hepatitis C.

Whatever the other related ramifications of these developments are, sub-standard drugs of dubious effectiveness are likely to have a seminally deleterious impact on the way we deal with sick children. From the perspective of our vocation, even at the best of times, looking after very ill children is a job that would tax the health services and healthcare personnel to the utmost. The very last thing we need in that equation is the added unpredictable denominator of inferior medicinal drugs of uncertain efficacy with the indeterminate potential to cause some complicated, undesirable and erratic side effects.

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