

# Promoting The Role Of Malaysian Non-Governmental Organizations In The Safety Of Medicines

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## Abstract

Non-Governmental Organizations (NGOs) recently have become the global voice of the people, as their needs and choices arise. The main aim of this short communication is to encourage NGOs in Malaysia such as Consumer Association Penang (CAP) and The Federation of Malaysian Consumers Associations (FOMCA) to participate in drug safety activities. We discuss the role of NGOs, why NGOs should be interested in drug safety, the need of the involvement for Malaysian NGOs in drug safety initiatives in Malaysia and the role of NGOs in consumer reporting of Adverse Drug Reactions (ADR) in Malaysia. We concluded that NGOs should play active and vital role to enhance drug safety activities in Malaysia

## INTRODUCTION

Adverse drug reactions (ADRs) can cause short-term and long term hospitalization and mortality .Despite all medicines benefits, evidence continues to mount that ADRs are common, yet often preventable cause of illness, disability and even death. ADRs are responsible for a significant number of hospital admissions ranging from 0.3% to 11%.<sup>1</sup> . A commonly quoted meta analysis performed in the United States indicated that ADRs were between the 4<sup>th</sup> and 6<sup>th</sup> most common cause of death in 1997.<sup>2</sup> The World Health Organization (WHO) defines an ADR as ‘any response to a drug that is noxious and unintended, and that occurs at doses used in humans for prophylaxis, diagnosis, or therapy, excluding failure to accomplish the intended purpose’.<sup>3</sup> There are few studies about ADRs incidence rate in developing countries. A prospective observational study from Iran identified that 11.75% of the patients had experienced at least one ADR.<sup>6</sup> In another study from Iran approximately 16.8% of the patients had at least one ADR and 2.9% of the ADRs was identified as lethal.<sup>4</sup> Another study from South India reported an overall incidence of 9.8%. This included 3.4% ADR related admissions and 3.7% ADRs occurring during the hospital stay.<sup>5</sup>

Pharmacovigilance as defined by the World Health Organization ( WHO) is the science related to detection, understanding, assessment and prevention of adverse drug reactions and any other problems related to drugs<sup>6</sup> . This science began 40 years ago. At that time of disaster of

thalidomide resulted in embryonic malformations of thousands of children whose mothers used the drug during pregnancy in Europe in the sixties; where the concerns of the world rapidly evolved. Topics were discussed and the interest in the safety of medicine emerged.

A non-governmental organization (NGO) is any non-profit, voluntary citizens' group which is organized at a local, national or international level. Task-oriented and driven by people with a common interest, NGOs perform a variety of services and humanitarian functions, bring citizen concerns to Governments, advocate and monitor policies and encourage political participation through provision of information. Some are organized around specific issues, such as human rights, environment or health. They provide analysis and expertise, serve as early warning mechanisms and help monitor and implement international agreements. Their relationship with offices and agencies of the United Nations system differs depending on their goals, their venue and the mandate of a particular institution.

## ROLE OF NGOS IN HEALTH AND DRUG SAFETY

NGOs have been defined by the World Bank as “private organizations that pursue activities to relieve suffering, promote the interests of the poor, protect the environment, provide basic social services, or undertake community development”. NGO activities can be local, national or international. NGOs have contributed to the development of communities around the world and are important partners of

many governments – while remaining independent from governments. According to the Human Development Report, there were over 37,000 NGOs in the world in 2002, a growth of 19.3% from 1990. Their purposes differ but overall two categories dominate: economic development and infrastructure (26%) and research (23%)

The involvement of civil society has profoundly affected not only the concepts underpinning public health but the formulations and implantations of public health programmes and policies as well. Non-governmental organizations and other civil society actors have engaged themselves to implement health programmes at country level, made to remote areas and populations possible, and advocated public health issues to a broad audience.

The growing role of these organizations and its importance has increase at the local level so that they become the global voice of the people and their needs and choices and advocate for their rights. These organizations include expertise with excellent skills that deal with people's issues and express their needs. They have an important and complementary role in linking and formation of networks and continue to play a useful role in the implementation of policies. They also have the ability to communicate with decision makers and with the various media to support and implement these policies. In addition, they have the ability to influence people's views and change those via. Moreover, these organizations have the ability to access a large segments of people and space capacity without pirochraty and without corruption, to take the cultural and social initiatives which cannot accessed by these governments.

### **WHY NGOS SHOULD BE INTERESTED IN THE SAFETY OF MEDICINES?**

Medicines have a big impact on the people and can cause adverse effects which can lead to mortality. They also have an impact directly or indirectly on the economic and social affairs. Every medication is potentially hazardous. Therefore, safe and effective drug therapy demands a profound knowledge of every drug product being prescribed, through patient analysis, and adequate patient education. If these three essentials are observed most drug-induced diseases and most drug-related malpractice litigations can perhaps be avoided.

To get a high level of health is one of the principles of the human rights that have been declared in the Alma Ata Declaration. This does not mean that health facilities must be available to all, but to enable people to participate, get equal

access to health services and ensure their participation in issues that affect their health and their participation in the formulation of policies that affect their lives. Therefore, NGOs can have a major role in pharmaceutical policy. The rational use and safety of medicines are of great value because they represent large segments of the population and their interests, protect consumers and should be relied upon to raise the degree of vigilance about the adverse effects of medicines<sup>8</sup> The urgent need is to access for everyone interested in the safety of medicines. More importantly, the integrity of NGOs as well as doctors, pharmacists, manufacturers, regulators, the media and consumers are the most important players in this area. Therefore, there must be full coordination between the active players with full transparency and through the participation of all.

What are needed to be done by the NGOs for the safe use of medicines?

To ensure better contributions for the safety of medicines, the following requirements should be fulfilled by the NGOs:

- They should have an active role in the formulation of laws related to pharmaceutical policy and the safety of medicines and ways to avoid the dangers.
- They should control and have observing role which must complement to government agencies on the safety of medicines.
- They should have the role of education, and awareness on the rational, safe use of medicines and basic health knowledge to ensure the proper use of medicines.
- They should protect certain categories of consumers, such as the elderly, children and women, of the dangers of certain drugs.
- They have to report and create awareness on the harmful effects of drugs and the importance of monitoring and reporting of fake medicines, unsafe or questionable or damaged medicines.
- They should announce consumers about the danger effect of certain drugs and when it withdrawal from the market and stop the circulation of these drugs.

All consumer complaints should be in coordination with the pharmacovigilance centers and other authority agencies.

NGOs can be good channels to express public concerns and problems as a result of use of these, dangerous life-threatening drugs.

### **THE NEED FOR THE INVOLVEMENT OF NGOS IN DRUG SAFETY ISSUES IN MALAYSIA**

Malaysia has a national centre of Pharmacovigilance namely the 'National Adverse Drug Reaction Monitoring Centre' that covers the whole country. Some major hospitals and pharmaceutical companies also operate ADR monitoring systems but all reports are consolidated by the national centre. The reports from doctors, pharmacists and dentists are on a voluntary basis but reports from marketing authorization holders are mandatory. They monitor drugs for human use, vaccines, biologicals and herbal remedies. National ADR centers use prepaid postage report forms or report card updated every month. They still record manually. They have a local database. The national centre has an advisory committee which makes the causality assessment of the reported ADRs.<sup>15</sup> The Malaysian Adverse Drug Reaction Advisory Committee (MADRAC) was established under the Drug Control Authority (DCA) to perform the function of monitoring safety profiles of drugs registered for use in Malaysia. MADRAC provides the DCA with information pertaining to drug safety issues which occur locally and internationally. The National Drug Safety Monitoring Centre, which is the Secretariat to MADRAC, was accepted as the 30<sup>th</sup> member of the WHO Safety Monitoring Program in 1990. Under the monitoring programme, all ADR reports, which have been received and screened by MADRAC, are submitted to the Uppsala Monitoring Centre in Sweden for inclusion into the WHO database.

The MADRAC also promotes ADR reporting in Malaysia and provides information and advice to the DCA in order that regulatory action can be taken based on the ADRs received (local and foreign). It also provides information to doctors, pharmacists and other health care professionals on ADRs and participates in the WHO ADR monitoring programme

An urgent need in Malaysia is to get NGOs involved in the safety of medicines because of the following reasons:

- A lack of awareness of drugs and their harmful effects between health workers or consumers are notified.<sup>17</sup>
- The existence of a program to monitor the safety of medicines in Malaysia through the spontaneous

reports received from doctors and pharmacists, the consumers have not had their official channel for the expression of their experiences.

- Malaysian program is still suffering from reporting. This problem hinders the availability of sufficient information on the harmful effects of drugs. 21
- The increasing use of medicines without supervision of medical doctors.
- The reports received by national pharmacovigilance centre about ADRs of the medications are still low in comparison to Malaysian population. 18, 19.
- The widespread use of herbal and traditional medicines in Malaysia, without the supervision of medical doctors.
- Limited role of NGOs.
- Limited role of mass media in drug safety education.
- Mechanisms to enable NGOs to participate in the safety of medicines

In line with the problems mentioned above, the researchers suggested the following mechanisms so as to enable NGOs to participate well in the safety of medicines:

- A full coordination between NGOs, those concerned in safety of medicines and the pharmacovigilance centers, are needed.
- It is imperative to initiate a program to educate people about pharmacovigilance, the goals and purpose of its mechanisms.
- It is recommended to teach and educate people about the harmful effects of medicines and pharmaceutical and medical errors through lectures, pamphlets and articles in the audio-visual media.
- Consumers, patients and the media should participate in medicine safety issues and report on adverse effects of drugs as a collection of such communications and dissemination of opinions could be useful.
- The prevention of disasters or serious counterfeit

medicines should be rapidly reported.

- NGOs are encouraged to provide assistance on advice and information for the public.

## **ROLE OF NGOS IN CONSUMER REPORTING OF ADRS**

Evidence from Swedish NGOs KILEN-Consumer Institute Medicines and Health, had documented that KILEN started consumer reporting of ADRs 25 years ago. It was the real start for consumers to be involved in drug safety issues. The consumer reporting, which was started by NGOs in Sweden, showed that consumer reporting of ADRs can add more benefits and advantages to the existing system of spontaneous reporting system.<sup>20</sup> The NGOs can play an important role in detecting, collecting and analyzing ADRs reports. NGOs can be the best channel for public to express their suffering and experiences about harmful effects of their medicines.

The existing system of monitoring ADRs depends on spontaneous reporting of health professionals as the main source for information. Spontaneous reporting is the most widely used method for pharmacovigilance. Despite its inherent limitations, the system provides vital information of clinical importance. These limitations include difficulties with adverse events recognition, underreporting, biases, estimation of population exposure, and report quality.<sup>7</sup> Patients, consumers and health professionals have the right to be involved to report their experiences and suffering as a result of these adverse effects which threaten their health and their lives.<sup>8</sup> The current system of reporting depends on the spontaneous reports written by doctors, pharmacists and when consumers involved in the process; this can reinforce their rights and achieve justice. The consumer's experiences and views can be used and could provide good tools for information about ADRs<sup>9</sup> This report increases the amount of knowledge which reveals significant indicators of the damage caused by medicine.

However few countries currently accept consumers reports; Sweden (1978), Denmark (2003), Netherlands (2004), USA (1993), Canada (2003), Australia (2003), UK (2005) and New Zealand<sup>10,11,12</sup>. The consumer can report directly to medicinal agencies or indirectly through consumer organizations or NGOs. They are also able to submit electronic reports or paper and telephoned reports. Experience in the Netherlands obtained during three years showed that patients' reporting can be good information

source for drug safety monitoring and has qualitative and quantitative value<sup>16</sup> The evaluation of the first 6 months of patients reporting of yellow card schema in United Kingdom showed that there were no differences in the proportion of serious ADRs reported, compared with reports of health professionals<sup>13</sup>. Blenkinsopp et al wrote a systematic review on patients reporting of suspected ADRs. The MHRA team showed more evidences and advantages from international experience regarding patients reporting. They concluded that there is a lack of publication about patients reporting of ADRs as the number of published studies is very small<sup>14</sup> A qualitative examination of patients' reports has shown that they were rich in terms of their description of nature, severity and significant of reactions<sup>15</sup> Authors from Sri Lanka suggested that consumer reporting is the best method for developing countries to overcome under reporting and can complement the existing system of reporting based on physicians and pharmacists<sup>22</sup>

## **IMPORTANCE OF THE CONSUMER REPORTING IN MALAYSIA**

Consumers are active players in drug safety and key stakeholders in relation to pharmacovigilance and can actively contribute through an integrated and efficient reporting system. Direct reporting is an essential tool to empower consumers and to improve their involvement in the management of their own health. With consumer reporting, ADRs will be detected earlier, more ADRs would be reported e.g. over the counter medicines. Consumer reporting can be a useful method to overcome under reporting. Consumer reporting can be a good solution for limitation of existing system based on health professional's reports. Consumer reporting will promote consumer rights. Consumer reporting cannot replace the existing system but can complement and strengthen it.

## **CONCLUSION**

In Malaysia, NGOs such as CAP and FOMCA should play an important role in detecting, collecting and analyzing of ADRs and other drug related problems. NGOs should coordinate with regulatory bodies and pharmacovigilance centers in the country to educate the public regarding drug safety and the harmful effects of medicines. The involvement of NGOs in drug safety activities can add more benefits and advantages to overcome under reporting, increase the knowledge about ADRs, promote consumer rights and improve patients' safety in Malaysia

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