Editorial note

When patient experienced failure in medication, and their condition got worse, some of them that were not well informed would blame it to their physicians. They doubted whether they got the wrong treatment, insufficient, or inappropriate medicament, and a fraction of them had the courage to sue their physician.

In some cases, worsening of the condition might be the result of malpractice, but some might be due to inappropriate treatment, the natural course of the disease, or drug adverse effect. Therefore, to prevent legal prosecution, a physician should always upgrade their knowledge, and be well informed in new drugs and their pharmacology.

The world of pharmaceuticals is commercial, where commercial interests could have been put before those of patients. Therefore, physicians may not rely on the information from medical detailers only, as they stress on the benefit. In this respect, drug information should be read carefully, the balance of benefit and harm weighted, and patient's response should always be noted, as there is racial, population, and individual variability.

Though the drugs are already approved by the authority, further testing of the safety and tolerability of the drug in the population should always be done in the form of post marketing surveillance, if possible by an institution without conflict of interest.

This issue of Med J Indones published a post marketing surveillance on fluvastatin XL in the treatment of hypercholesterolemia by Setiawati A and Darmansjah I.[1] The authors concluded that treatment with fluvastatin XL 80 mg once daily for 8 weeks was safe and well tolerated, and also effective in reducing total and LDL cholesterol, as well as triglyceride, and in increasing HDL cholesterol in clinical practice. This post marketing surveillance was conducted for a very short time, using limited patients (566), while the drug might be used for long term therapy. Therefore, we can say that the drug is safe when it is used no longer that 8 weeks, but the safety can not be guaranteed for a longer time of use.

Moreover, the patients were gathered from all over Indonesia with many ethnics, but the various ethnics were not included in analysis, may be due to the limited number of patients. This study, as many other post marketing surveillance, was funded by a pharmaceutical company (PT Novartis Biochemie), the manufacturer of the drug,[1] and therefore was not free from conflict of interests.

Funding of a clinical trial and post marketing surveillance of drugs by the manufacturers do not exclusively happen in Indonesia. In the US, the Food and Drug Administration (FDA) that should test drugs and conduct post marketing safety studies, relies on pharmaceutical companies to design and conduct the clinical trials and post marketing safety studies that evaluate the drug efficacy and safety, and most of the studies requested are not done. The companies even pay the salaries of the FDA personnel who make the decisions whether the drugs are approved or not.[2]

When things go wrong, the patient might sue the physician, and in certain cases, the pharmaceutical company. Though unusual, in Europe a few claimants were financially compensated due to vaccine side effects.[3] Therefore, to avoid legal prosecution due to serious adverse drug reaction, a pharmaceutical company should ensure that the drug released to the market is really safe, and follow the effects of the drug in the population by conducting proper post marketing surveillance.

Another issue is the hot news of contamination of powdered infant formula and baby food by *Enterobacter sakazakii* that triggered a polemic. A researcher (Budiarti S) from Bogor Agriculture University published a post marketing safety study on infant formula that was blown up by the media. The report of the study can be found at www.ipb.ac.id dated the 1st of July 2001, but just recently, the result of this study is being followed up by the Food and Medicine Supervision Board (BPOM) to assess the risk of the contamination according to the guidelines recommended by the WHO.[4] Actually, the BPOM and the powdered formula milk and baby food producers should respond earlier to avoid public anxiety and victims if the contamination turns to be harmful.

E sakazakii is reported to cause fever, diarrhea, enteritis, and meningitis in premature and low birth weight babies,

in many countries.[5] Therefore Indonesian pediatricians should be aware, and look for the etiology, so that the cases, if there is, can be reported.

In conclusion, post marketing surveillance is important both for patient/consumer safety as well as for physicians and companies to avoid legal prosecution.

References:

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