Risk Communication Regarding Drug Safety in Japan

Michiko Yamamoto*

Education Center for Clinical Pharmacy Practice, Showa Pharmaceutical University, 3-3165, Higashi-Tamagawagakuen, Machidashi, Tokyo, Japan

***Corresponding author:** Michiko Yamamoto, Education Center for Clinical Pharmacy Practice, Showa Pharmaceutical University, 3-3165, Higashi-Tamagawagakuen, Machidashi, Tokyo 194-8543, Japan, Tel:+81-42-721-1511; Fax +81-42-721-1588; E-mail: m-yamamoto@ac.shoyaku.ac.jp

Received date: Feb 25, 2014, **Accepted date:** Mar 20, 2014, **Published date:** Mar 27, 2014

Background

For individual and for public health, drug safety has significant implications on a large scale. Given the inherently uncertain safety and effectiveness of drugs, discussion of the significance of benefit/risk communication with stakeholders including healthcare professionals and patients has been repeated [1-4]. In pharmacovigilance, risk communication has an enormous role with the object of measures for drug safety and its importance would be recognized. According to WHO Glossary of terms used in pharmacovigilance, risk is defined as the probability of harm being caused; the probability (chance, odds) of an occurrence [5]. Risk communication is one of the composing element in risk analysis along with risk assessment and risk management in the field of food and environmental issues [6]. Risk communication is an interactive process of exchange of information and opinion on risk among risk assessors, risk managers, and other interested parties in protecting the public health [7]. All stakeholder groups should be ideally involved from the start. The communication is aimed to offer essential information so that consumers can make an independent decision about risks. People need to know the risk which affects their health and safety and they need to decide a proper way to cope with the risk. Regulatory bodies and companies responsible for public health and safety should identify potential risk, assess, and decide the appropriate measures to execute them. Therefore, it becomes important for the government to grasp the level of the understanding of the risk or what kind of behavior has been performed [8]. Along with risk evaluation Ń a a a `oaatoa ϰ3 respq

The regulatory bodies, healthcare professionals and pharmaceutical companies should develop a system for risk communication with patients in order to disseminate the information on adverse reactions and promote the proper use of the drugs for patients.

The scheme for Patient reporting of Adverse Drug Reactions should be established.

The regulatory bodies should review and improve several safety information which also includes “Dear Healthcare Professional Letter (DHPL)" which is currently provided to healthcare professionals.

The regulatory bodies should also consider various measures to provide information for patients, including dissemination of the information focused on adverse drug reactions.

The regulatory bodies should confirm whether pharmaceutical companies appropriately implement safety measures, including provision of information to healthcare professionals. According to these concrete proposals, the operation of the drug adverse reaction reporting system by patients was started and the other issues would be in process and an effort would be made. Since April 2012, Risk Management Plan (RMP) has been imposed to the pharmaceutical companies (Figure 1).

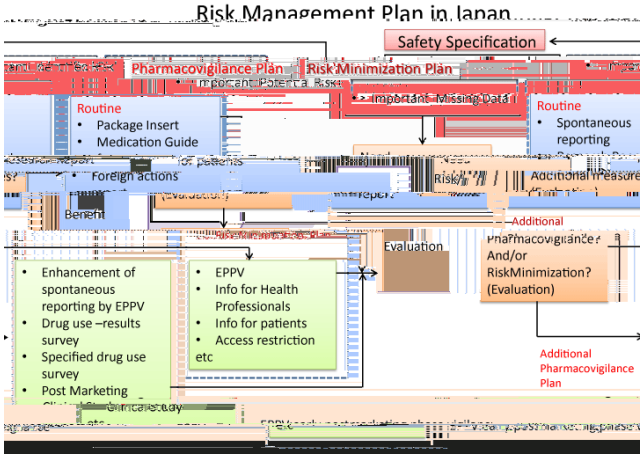

Figure 1. Risk Management Plan in Japan

From the drug development, drug approval to post-marketing in all periods, the risk evaluation and review of the drugs are carried out. Safety measures for post marketing with an explicit prospect should be implemented by pharmaceutical companies.

Approach Risk Communication in Japan

It has been considered that to ensure the safety of drugs in Japan, there were several items which were not efficiently executed in terms of involvement of patients, though the framework or law had been set up. The following issues are considered that should be improved; Risk information should be provided to patients and consumers as well as healthcare professionals concurrently by regulatory agencies and pharmaceutical companies in order to share it with them.

1) Risk information should be provided to patients and consumers as well as healthcare professionals concurrently by regulatory agencies and pharmaceutical companies in order to share it with them.

2) Risk information should be made easily available and accessible by public through web sites including regulatory agencies in any communication tools.

3) Considering the patient’s health literacy level, appropriate risk information should be provided by regulatory agencies.

4) The leaflets containing the patient information should be evaluated for understandability and accessibility by conducting user testing periodically.

For the risk communication, transparency, interactivity and sharing the evidence based information are significant which composes elements and consumers or patients to be involved in the risk communication. With introduction and advancement of IT technologies, wide range of drug information is easily available for the people. But as the information contents are multifarious, it is necessary to show what appropriate and evaluated information for them is. The drug information has high specialty, hence it would be difficult for consumers or patients to understand correctly. Therefore, it is necessary for healthcare professionals to make it easy for them to understand. Under this situation for the drug safety, the importance of risk communication has been recognized and it should be reinforced in future.

References

1. Urushihara H, Kobashi G, Masuda H, Taneichi S, Yamamoto, et al. (2014) Pharmaceutical company perspectives on current safety risk communications in Japan. Springerplus 24: 3-51
2. Bahri P, Harrison-Woolrych M (2012) How to Improve Communication for the 01 IT