

Harmonization with society

● Communication with External Bodies and Organizations

Overcoming the wide range of environmental issues requires adjustment to the conflict of interests and role delegation. To establish communication based on a trusting relationship between the concerned parties and bodies essentially requires that environmental issues are addressed.

Scientific approaches such as Life Cycle Assessment and Supply Chain Management are effective in assessing the environmental load

generated by business activities, however, in order to apply the results of assessment in such a way as to understand the actual state of affairs at each level, and to devise specific measures to address the issues, a set of fair and efficient rules needs to be established involving all concerned parties. The JPMA Environment & Safety Committee communicates with a wide range of concerned parties and bodies and proactively promotes information sharing and cooperative efforts in solving the issues.

Member Companies' Reports of Societal Nature

Two-thirds of JPMA member companies publish reports that include content related to environmental actions. This practice is firmly established in the firms that cause large environment loads. Following a recent surge in CSR philosophy, these reports are rapidly evolving from a mere environmental report to environment & social reports, a CSR report, or a sustainability report to encompass the social aspects and issues, and to take on a role as a communication tool with the stakeholders. There are some

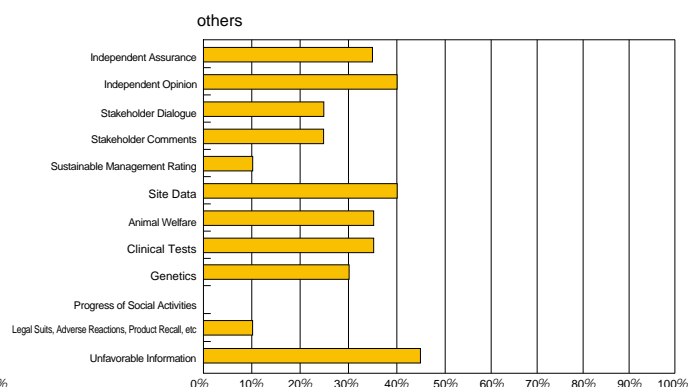
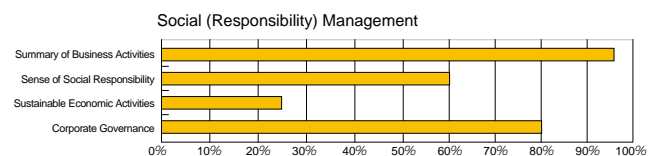
common standards and a unified look to the way information related to environmental issues is disclosed, as each company follows the Ministry of Environment's "Environment Report Guidelines". On the other hand, however, the current situation is that the reporting and information disclosure of activities of a societal nature varies widely in terms of either quality or quantity, despite the existence of international guidelines such as the "GRI Guidelines".

State of "Reports of a Societal Nature"

The latest reports published by member companies in 2006 were examined to analyze trends in the disclosure of information of a social nature.

Reports from 20 companies that were published by the end of October 2006 were read and items related to social management, social performances and so on were examined. The items frequently appearing and related to management were: a "Summary of Business" (19 companies) and "Corporate Governance" (16 companies). The items frequently appearing and related to performance were: "Supporting Community / Communication" (20 companies), "Safety and Health of Employees" (20 companies), "Managing Health of Employees" (19 companies), "Supporting Society and Culture" (19 companies), and "Compliance" (18 companies). By contrast, less than a half of the reports had items related to "Enhancing Human Rights" (seven companies). Compared to the year before, more reports included items specific to the pharmaceutical company such as "Clinical Trials" (seven companies), "Animal Ethics" (seven companies), and "Genetic

Research" (six companies). Another characteristic of the social report was in many cases its function as a message to stakeholders, such as patients and healthcare professionals, through a theme article about social contribution in the form of medicine provision, the real business of the industry. However, with regard to the most important issue of information disclosure, negative information disclosure was often seen in environmental reports, such as soil pollution cases and environment-related incidents, while only a few societal reports included items about drug recall cases or court cases, and a majority of the companies still seem hesitant to disclose this information.





Situation surrounding Pharmaceutical Firms with Foreign Affiliation

Reports from pharmaceutical companies affiliated with a foreign corporation (two American & two British) for global development were examined for comparison. Our overall impression was that many innovative ideas are used in designing an easy to read, understand, and become familiar with, report on company activities that incorporates many visual aids such as photographs and diagrams, and a story-like narrative in the articles. Detailed information such as environmental load data, etc., is found elsewhere, eg company website. These reports seemed to make more of a conscious effort to provide information through maximum

utilization of each medium to all types of stakeholders. Other characteristics not seen in Japanese companies' publication is the disclosure of concrete figures / data in the societal portion of the report. Data such as the number of laboratory animals used for research, number of animal laboratories, cases where breach of compliance occurred in business / marketing departments, amount of financial support / donation to community, cost of drugs offered for free to disaster-stricken areas, quantity of HIV drugs provided at special pricing to developing countries, number of female staff in management positions, etc. are clearly stated, for example.

For the Future

In terms of appropriate information disclosure to stakeholders, reports of a societal nature, in general, seem to reflect too much corporate publicity activity and not enough function as a tool for fulfilling CSR, due to a lack of corporate societal activity management. Each company should make an effort to create robust

policies for implementing societal actions based on its experience in terms of environmental action and create an environmental report publication that will disclose information, including negative information, following common unified standards.

Federation of Pharmaceutical Manufacturers' Associations of Japan

Packaging investigational group

Pharmaceutical containers and packages display information such as the recycling information stipulated in "Guidelines for Distinctive Labeling of Containers and Packaging for Pharmaceuticals, etc." issued by the Federation of Pharmaceutical Manufacturers' Associations of Japan (FPMAJ), and information about specifications, forms, labeling, etc., that are important to prevent accidental use.

FPMAJ set up an investigational group in July 2006 to handle issues such as amendment to the Containers and Packaging Recycling Law, handling of healthcare waste such as aerosol cans and syringes used for self injection, and revision of the recycling symbol and push-out symbol on PTP packaging for tablets and capsules. Two members from the JPMA Environment & Safety Committee currently participate in this group in cooperation with other committees.

Healthcare Related General Waste Control Project

The progress made in home-based healthcare has increased the incidence of drug administration by patients through means such as self-injection. When prescription drugs, usually used in hospitals, are administered at home, their proper use, management, and disposal are essential as many prescription drugs have a high efficacy. While home-based healthcare has many advantages for the patient's quality of life, it is necessary to create a proper framework for the safe disposal of used injection needles and medicine no longer needed.

Association, etc. have participated to create a system for the proper disposal of used injection needles, disposed medicine, and aerosol drugs from a patient's residence.

In response to this trend, FPMAJ launched the Healthcare Related General Waste Control Project in February 2005. While FPMAJ acts as the executive office for this project, other concerned parties such as JPMA, Japan Self-Medication Industry, Japan Generic Pharmaceutical Manufacturers

A project leader and two more members from the JPMA Environment & Safety Committee are investigating what can be done from a wider manufacturers' perspective. The Project demands investigation through a delicate liaison between the concerned parties that, for instance, consists of listening to views of the Ministry of Health, Labor and Welfare, and exchanging information with the Japan Pharmaceutical Association. Another effort in understanding the reality of the frontline is visits to the health insurance pharmacy (Related article can be found on page 20 of this report).

Following up Nippon Keidanren Environment Voluntary Action Plan

The Nippon Keidanren runs an annual follow up session to its Environment Voluntary Action Plan, and we take part in this session in conjunction with the Federation of Pharmaceutical Manufacturers' Associations of Japan (FPMAJ). We call for

participation from all JPMA member companies whose participants extend to organizations under the FPMAJ, as well as conduct a follow up investigation, collate and analyze the data, and submit the results to the FPMAJ.

Global Warming Prevention Measures

Sixty-seven JPMA member companies and seven firms from FPMAJ federated bodies participated in the follow up investigation in FY 2005. Based on the results, the Energy Saving / Global Warming Prevention Groups created a Keidanren report for each

individual industry type that was submitted to the FPMAJ. "A Report of Investigation in Energy Saving / Global Warming Prevention Measures by Pharmaceutical Firms" was also distributed to the companies participating in the follow up.

Waste Management

Seventy-six JPMA member companies and seven firms from FPMAJ federated bodies participated. The results of investigation were collated into a report by the Resource Conservation / Waste Management Groups and submitted to the FPMAJ. "A Report of

Investigation in Resource Conservation / Waste Management Measures by Pharmaceutical Firms" was also distributed to the companies participating in the follow up.

Japan Medical Wastes Research Association

The medical waste issue requires understanding and cooperation by medical institutions, the patients, local governments, waste processing businesses, pharmaceutical companies, etc., to reach a solution. This issue also requires specialized knowledge from the experts to create the system with safe processing mechanisms and

a framework for handling infectious wastes, and bearers of processing costs. The vice chair of the JPMA Environment & Safety Committee is a member of this research association who takes part in selection of the topics for discussion.

TOPICS

Conversation with the Concerned Parties on Medical Waste Management Measures

1. Japan Medical Wastes Research Association

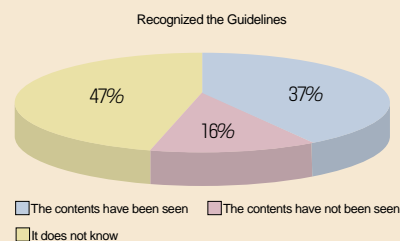
In order to investigate the issues related to healthcare-related waste, JPMA takes part in the Japan Medical Wastes Research Association, the only academic body in Japan that is specialized in healthcare waste issues and continues to act. A JPMA representative took part in the panel discussion "Strategic Management of Medical Waste" at the 25th Research Conference as a panelist, and reported the state of our actions such as promoting 3R efforts for drug containers and packaging and efforts for the proper disposal of home-based healthcare waste. Another action discussed was our continuing efforts to confer with authorities, healthcare professionals, waste disposal operators, etc., about the issues of proper disposal of infectious wastes from hospitals, etc. We will continue to seek proactive involvement in the proper disposal of medical waste.



Japan Medical Wastes Research Association the 25th Research Conferences

2. Questionnaire on the "Guidelines for Disposal of Pharmaceutical Containers and Packaging"

JPMA created and published the "Guidelines for Disposal of Pharmaceutical Containers and Packaging" along with the Japanese Society of Hospital Pharmacists in 2002. A questionnaire was administered in February at over 50 hospitals in Japan this year to investigate the state of use of this resource. About 50% recognized the "guidelines", suggesting that there is room for improvement in publicity promotional activities. On the other hand, all hospitals that responded, including those that did not recognize the "guidelines", stated the "guidelines" are / would be useful. Therefore, the effectiveness of the "guidelines" could be verified. We will revise the content of the "guidelines" to make it more useful on the healthcare frontline.



3. Disseminating Information

Proactive information disclosure to and communication with the concerned parties are essential in overcoming various environmental issues, and this "JPMA Environment Report" is an important tool. Other efforts in disseminating information have also been made this year. One such effort was an article in the Monthly Pharmaceutical Affairs May 2006 issue reporting the outcomes of waste control measures in the pharmaceutical industry. This article emphasized the home-based healthcare waste issue as a future issue and how it is currently being investigated by the industry. Also, as the pharmaceutical industry handles many chemical substances, a commentary on chemical substance control (safety and environmental consideration) was published in "Chemical Substances and Environment" (Vol. 75).

As you can see, we endeavor to publicize JPMA' efforts and exchange information. We will continue to collaborate with the concerned parties to address healthcare waste issues.

On Healthcare Related General Waste Control Project

Takeaki Ota,
Japan Pharmaceutical Manufacturers' Association

Generalization of home-based healthcare in response to the rapid aging of society means we are seeing more incidents of healthcare related waste such as injection needles coming from the home and into the general waste.

The logic that the amount of drug administered should be based on the predicted required period has made the prescription and administration of long-term drugs possible. This has led to increased chances of unused prescription drugs turning up in general waste. Also, recently many highly efficacious (with strong therapeutic effects) pharmaceuticals have been developed and marketed.



Pharmacy visit investigation

● Issues Raised by Healthcare Professionals

On March 30th 2005, a session named "Regarding addition of drugs subject to home based self injection supervision and management fees" was held at the Central Social Insurance Medical Council Consultation Cost Basic Issue Subcommittee. There were many discussions, aside from the main topic, which were related to issues concerning the waste from home-based health care. The healthcare issues most strongly raised by the committee members are presented in the lengthy quotes below:

- This is something you would not want to think about, but, for example, if the patient passes away halfway through therapy, what do you do with the unused drugs, including the needles... in terms of management of such a situation, a proper set of rules must be created, this is an important request.
- I think, as far as the infectious wastes are concerned, a framework should be created by pharmaceutical companies for the manufacturer and/or MHLW to manage properly, so that there is no damage or nuisance to the citizens.

- Not just needles. For example, there are those new anti-rheumatoid drugs some are in rubber top vials that must be stuck by needles, so these cannot be disposed of in household trash. The syringe, of course, also has to be put into the infectious waste bin.

- How to deal with the possibility that infectious wastes get mixed in with general trash, and how can they be separated? They promote sorting garbage, telling us to separate iron from aluminum. But for us, the biggest problem is to separate the infectious wastes from general household garbage.

This is indeed the problem for all of us pharmaceutical companies, pharmacies and medical institutions. The pharmaceutical companies are required to act beyond merely stating, "Do not give away. If unused, ask at the pharmacy or medical institution about proper disposal." Also comply with waste disposal rules set by the local government."

● Project Launch

The "Interim Summary Regarding Revision of Containers and Packaging Recycling System" in July 2005 was to prioritize containers and packaging in general, including spray cans, under the recycling of resources. In response, a submission was made to the ministries, METI and MoE under the name of the FPMAJ Safety Committee, with the main points as follows:

- Efforts to reduce waste from packaging are of course necessary for medical products, however, the risks to human life and human health should be given a higher priority than resource recycling. Therefore, it is not appropriate to allow drug-contaminated containers and packaging to enter into the recycling system.
- In order to avoid the risks to health and the environment from home-based healthcare wastes, including medicine-contaminated containers and packaging discharged from the general household, the concerned parties should investigate the methods and protocols from the time of collection to final disposal, etc.

Investigation of the proper disposal of healthcare-related waste from households and issues surrounding revision of the Containers and Packaging Recycling Law have been carried out since August 2005 by

the Packaging Issue Investigation Group, restructured PTP Packaging Issue Investigation Group, under the Safety Committee.

However, in order to create a system for proper processing based on the risks, it was necessary to facilitate discussion among the members without being under the authority of the Safety Committee. Therefore in February 2006, as a part of drug safety measures, in conjunction with the various institutions and organizations, the Healthcare Related Waste in General Disposal Control Project was launched to set up a recycling route that enables the proper processing / disposal of such wastes.

Items of investigation for this project include: (1) What to do with unused drugs? (2) Are there risks with disposing of not only injection needles, but the vials stuck with the needles and syringes, into household waste? (3) Is separating the infectious waste from general household garbage not more important than sorting iron from aluminum? Also, issues related to containers and packaging contaminated with highly toxic drug residue as well as the risks of accidental aerial discharge and inhalation leading to health damage from aerosol preparations such as asthma drugs are being subject to investigation.

● Collection and the Roles of Pharmaceutical Firms

During this project, all possible measures to address the above-mentioned issues are being investigated and discussion is in progress with the concerned parties.

- Where should such waste from home be taken to?

Possible channels include health insurance pharmacies and healthcare institutions.

In order to prevent misuse or inappropriate handling leading to accidents involving the patient, family, or the local government's cleaning operation contractors, at the same time pharmacies educate patients about proper drug use, it is desirable to also set up a specific system to collect used injection needles and unused drugs for disposal. Several cities, towns, and villages have a used injection needle collection scheme in place. The local pharmacists associations in Kawasaki city, Yokohama city, Kagoshima Prefecture, Funabashi city, Yotsuka city, Inzai city, etc., run such a system in conjunction with the authorities.

- We pharmaceutical companies should not just pass the load onto the institutions and pharmacists at health insurance pharmacies.

For example, a system in which each pharmacy calculates the costs and then the pharmaceutical companies pay the cost proportional to the sales only leads to inflated administrative costs. The system should be that the social reward is paid directly where the costs are incurred.

The health insurance pharmacies, etc., have to pay the processing cost until the system is set up. Possible actions by the pharmaceutical industry include financial contribution to the Pharmacist Association and other bodies, providing collection receptacles, creating and providing promotional posters and explanatory documents, etc.

Currently the Project in cooperation with Japan Pharmaceutical Association is examining a proposed system so that the scenes and voices from the frontline are seen and heard. We endeavor to seek what the pharmaceutical companies with the most access to information about the efficacy and risks of manufactured drugs can do, and to create an effective system in society in collaboration with the concerned parties.