

# Serving Our Customers

The Nippon Kayaku Group strives to provide its customers with the best possible products and to maximize their profits. To make this possible, we make every effort to ensure the safety and reliability of our products and services.

## R & D Organization

The Nippon Kayaku Group has established the Research & Development Group in order to respond changes in business climate including the diversifying needs of its customers and to accelerate product lineup revamping activities. Consolidating our management resources and R & D functions as well as fusing together our diverse proprietary technologies and intellectual properties has enabled us to create a R & D structure that allows us to display our strengths on a company-wide basis.

Joint research and participation in various forms of collaborative initiatives and projects with other domestic and foreign companies, public agencies, and universities allow us to keep abreast of cutting-edge technologies and continuously advance our technology platform. As part of these initiatives, we have established a corporate theme system specifically designed to generate new businesses and products. For example, we are currently working to develop a dye-sensitized solar cell that combines our newly developed dyes and resins as a means to developing a new type of eco-friendly energy.



Dye-sensitized solar cell currently under development

## Relationship Building through MR Activities

The activities of our medical representatives (MR) focus on the provision and collection of information regarding the safety of our proprietary ethical drug products. In recent years, expectations have grown for the MR to play an integral role as a member of the broader medical care community. This is because opportunities have increased for MRs, who have attained a comprehensive knowledge of medicine, to help create the best possible and most cost effective treatment option for patients.

Because we are a provider of numerous anti-cancer drugs, we recognize the importance of our mission more than most companies. We have established a presence as one of the top providers in the industry of anti-cancer drugs, and so we maintain an unwavering commitment to collecting the latest information on medicine and pharmaceuticals in order to fulfill

our responsibility to society. All of our MRs are keenly aware that on the other side of their daily meetings with medical staff stands a patient. The key to continually providing the best possible product is determined by continually supplying the most appropriate.



MR using Low-emission vehicle to visit a customer on business.

## Voice

### Striving to Collect and Provide the Most Appropriate Information on Ethical Drug Products



Tomokazu Shimada  
Chiba Office

Some of our anti-cancer drugs are used for the treatment of rare cancers. However, as long as there are cancer patients, pharmaceutical companies have a responsibility to deliver anti-cancer drugs to patients. Anti-cancer drugs are also known to cause side effects during treatment in most cases, so we believe our inherent strength lies in our expertise and database of information on our broad lineup of anti-cancer drugs. In leveraging this strength, we are convinced daily efforts are vital, which includes not only providing information to medical staff, but also actively collecting correct information on side effects.

## Our Initiatives in Ethical Drug Product and Medical Device Safety

Among its initiatives in ethical drug product and medical device safety implemented over the last year, Nippon Kayaku's drug for acute cardiac failure was subject to a re-examination\*1 that confirmed there was no change in the efficacy or safety of the product from when it was first approved. We also revised the precautions of use in the package insert for ethical drugs and medical devices we sell based on side effect information collected during our safety control initiatives. In turn, this information (13 ingredients, 13 cases) was provided directly to medical care practitioners in an effort to reduce risk to patients.

\*1 Re-examination: Refers to a review conducted on the actual track record over a predetermined time period to reconfirm the safety and efficacy of an already approved new drug product that contains different effective ingredients, indication and dosage regimen compared to conventional drug products at the time of approval.

## Our Initiatives to Eliminate Unapproved and Off-Label Drug Products and to Develop Medical Devices in Demand

There are ethical drugs, indications and medical devices that have yet to be approved in Japan, despite being approved in other countries, on the basis that few patients use these products and clinical trials in Japan would be too difficult. The Ministry of Health, Labour and Welfare (MHLW) is conducting research on unapproved or off-label drug products and medical devices that are required for medical treatment purposes in Japan and is moving forward with recruiting private sector companies for development as well as building a framework such as new drug applications based on evidence in the public domain.\*2

Among these measures implemented by the MHLW, physicians, medical institutions and patients advocacy groups have asked for additional indications regarding nine off-label indications for five of Nippon Kayaku's branded anti-cancer drugs. Regarding this, MHLW review meetings are taking place based on data submitted by Nippon Kayaku, while the Prescription Drug Subcommittee is also examining the validity of medical needs and NDA based on evidence in the public domain. For those products that the MHLW is likely to request development, Nippon Kayaku is currently moving forward with preparations for new drug applications for these off-label drug indications.

In addition, a list of medical devices in demand has been compiled. With regards to embolizing material which can also be used to treat cancer, Nippon Kayaku has applied to be a developer, concluding an agreement with a foreign company for the medical device materials. Currently we are moving forward with preparations for the development of two medical devices.

\*2 NDA based on evidence in the public domain: A procedure of applying for manufacturing and distribution approval where part of the application materials are exempt when recognized as publically known from a medical and pharmaceutical science standpoint (Ordinance for Enforcement of the Pharmaceutical Affairs Act Article 18 3-2).

## Information Provision and Management

### Management of Personal Information

In recognizing the importance of personal information, Nippon Kayaku has instituted a Personal Information Protection Policy in regards to the personal information it handles. In addition, we have established internal rules on the acquisition, use, provision and management of customer personal information. Training programs are also held to educate executives and general employees on these rules. Through these initiatives, our goal is to deepen the understanding of and raise awareness among all employees regarding the importance of safeguarding personal information as well as ensure best practices in the handling of personal information in daily work processes. Please see our corporate website for more information on our handling of personal information.

WEB <http://www.nipponkayaku.co.jp/english/privacy.html>

## Chemical Substance Information Management and Provision

A Material Safety Data Sheet (MSDS\*3) provides information necessary for the customers' safe handling of chemical substances and is required under the laws such as the Pollutant Release and Transfer Register (PRTR) Law and the Industrial Safety and Health Law of Japan. We use a database to manage the distribution of MSDS to ensure that the latest information is made available at all times. In fiscal 2009, we launched a new system capable of automatically producing MSDS in multiple languages in order to address new MSDS and GHS\*4 legislative requirements around the world and in Japan. In addition, we have begun development of a chemical substance control system that centralizes information on chemical substances. Starting with quantity control information required under the Amended Chemical Substances Control Law\*5, we plan to link this new system with other internal systems to create an integrated system that can provide and manage chemical substance information more precisely than ever before.

\*3 MSDS (Material Safety Data Sheet): A document issued by the supplier of a chemical product to the user to ensure its safe handling. The MSDS includes detailed information on the danger and hazardousness, safety measures, and emergency countermeasures.

\*4 GHS (Globally Harmonized System of Classification and Labeling of Chemicals): The danger and hazardousness of chemical substances are classified according to a certain standard and labeled in an easily understandable way. Product labels and MSDS follow these rules to prevent accidents and to protect human health and the environment.

\*5 Amended Chemical Substances Control Law: Requires companies to report the manufacture, import quantities and uses of all chemical substances annually.

## Ethical Drug Information

As of September 2010, Nippon Kayaku supplies a total of 74 ethical drug products and medical devices.

The Medical Information Service Center received a total of 24,000 inquiries from customers over the last year. The Center addresses each call in a professional manner so as to provide the most appropriate drug product information to ensure that our products are the best possible solution. Feedback received from our customers is also reported to relevant divisions. Our motto is to strive to raise the bar for customer satisfaction and promote the appropriate use of our ethical drug products.



Medical Information Service Center