日本漢方生薬製剤協会

JAPAN KAMPO MEDICINES MANUFACTURERS ASSOCIATION (JKMA)

GUIDE 2022

jKMA

Message from Chairman

FY2022 marks the second year of the first five year action plan for realization of the Future Vision for Kampo Medicines 2040.
The Forum: The Vision for Kampo Medicines and Public Welfare has been convened eight times to date.
One outcome of its recommendations was that "Basic Concept on Bioequivalence Evaluation for Addition of Formulations with Different Dosage Forms in Ethical Kampo Formulations" was issued as an administrative notice by the Ministry of Health, Labour and Welfare on July 19, 2021. The development of new formulations of ethical Kampo formulations was previously considered difficult but we are confident that the publication of such a guidance will benefit patients and the general public alike.
In addition, we launched a research grant to promote research into medical economics in fields in which Kampo medicines can be expected to be effective such as geriatric diseases and supportive care in cancer, with May 1, 2022 to March 31, 2023 as the research period. Grants have been provided for four research themes. We expect this project will help us identify medical economics researchers and expand the scope of research domains, and the research findings are expected to help accelerate the accumulation of evidence.
In the FY2022 drug price revision, ten Kampo products for ethical use and three crude drug ingredients were approved for re-examination for product unprofitability and upward price revisions.
Such approval was issued for ethical-use Kampo products for the first time in FY2020 (three products) and has been issued for more products this time around. Similarly in the case of ethical-use crude drugs, the 62 raw drug ingredients that were included in defined basic drugs in the FY2018 drug revision are still included in defined basic drugs. In order to maintain a stable supply of safe and reliable ethical-use Kampo products for the Japanese public, JKMA will continue to do its best to ensure that drug prices are maintained through their inclusion in defined basic drugs and approval for their re-examination for product unprofitability and upward price revisions.
Regarding promotion of the use of OTC Kampo products and crude drug products, the self-medication taxation system originally introduced as a time-limited taxation system will now be extended for a further period of five years from 2022. A further 42 ingredients that were not on the Rx-to-OTC switch list are now covered by the system, and also among OTC Kampo products/crude drug products, many products that contain the three crude drugs Ephedra, Lumbricalis and Nandian Fruit now qualify for the system. JKMA sees this as an opportunity to make Kampo and crude drug products more readily available to the Japanese public and is supporting calls for revisions such as making the taxation system permanent and making all OTC drugs qualify for the system.
We will also continue conducting awareness raising activities, including providing information to increase the rate of utilization.
Regarding the crude drugs from which Kampo products and crude drug products are made, JKMA will seek to encourage and expand the cultivation of domestically produced crude drugs to ensure stability. To maintain and develop good relations with China, the world's largest supplier of crude drugs, we will promote exchange between Japan and China, including exchanging opinions and information in online meetings with the China Chamber of Commerce for Import & Export of Medicines & Health Products. Looking to expand production of domestically produced crude drugs, we will take advantage of the Sustainable Production Strengthening Measures Project run by the Ministry of Agriculture, Forestry and Fisheries and, in cooperation with the Ministry of Agriculture, Forestry and Fisheries, the Ministry of Health, Labour and Welfare and other agencies, we will continue holding community briefing and consultation sessions to promote the development of domestic production areas for medicinal crops, thus helping realize a stable supply of high quality crude drugs.
To improve the quality of the crude drugs for Kampo preparations, we will also promote enhancement of the content of standards including proposing listing in JP and non-JP crude drug standards. In addition, we will hold seminars and workshops for JKMA members to bolster the Kampo GMP framework, ensure thoroughgoing quality management, and stabilize the supply of high-quality Kampo products.
Recently, there has been a spate of quality violations in Japan's pharmaceutical industry and unfortunately some of our members have also been involved in such quality violations. JKMA provides appropriate guidance and useful information to its members and holds regular study meetings for them, in the hope that the senior executives at all member companies demonstrate a policy of compliance to all their employees. JKMA and its members will renew their efforts to raise compliance awareness and promote activities to strengthen the compliance framework of member companies.
In 2023, JKMA will celebrate the 40th anniversary of its founding. In FY2022, member companies will work as a united team to realize a sustainable society through environmentally friendly activities whilst at the same time preparing to mark this anniversary. Member companies will cooperate closely with each other as they strive to contribute to public health and medical care by maintaining a stable supply of high quality Kampo products and by ensuring even greater product safety and encouraging the proper use of products.

Terukazu Kato, Japan Kampo Medicines Manufacturers Association

JKMA Outline

Pharmaceutical manufacturers association made up mainly of manufacturers and distributors of Kampo products and crude drug products made from crude drugs, and crude drugs. Industrial body affiliated with the Federation of Pharmaceutical Manufacturers' Associations of Japan (FPMAJ).

Member companies 61 (as of October 1, 2022)

Main aims

- ■ Stable supply of high-quality Kampo products, crude drug products, and crude drugs.
- ■ Disseminating and developing Kampo products, crude drug products, and crude drugs.
- ■ Contributing to the growth of the pharmaceutical industry and the health of the nation

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Senior Executive Advisor

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Advisor

Yasuto Mitani Kanebo Pharmaceutical Co., Ltd.	Hidetoshi Imaizumi Daiichi Sankyo Healthcare Co., Ltd.	Masao Onishi Kotaro Pharmaceutical Co., Ltd.

*Alphabetical order of company name.
*For Senior Executive Advisor and Advisors, the company name is shown at the time of their retirement.

The Future Vision for Kampo Medicines 2040 - Responsibility for People's Health and Healthcare -

In May 2018, the Japanese government released the prospect for future social security in 2040. The report predicts that Japan's elderly population will peak in 2040. To contribute to people's health and healthcare in an aging society, for instance, extending healthy life expectancy by supplying Kampo products and others based on crude drugs, we have established "The Future Vision for Kampo Medicines 2040 - Responsibility for People's Health and Healthcare -."

Vision 1 We will accumulate scientific evidence under industry-government-academia cooperation and enhance the usefulness of Kampo products and others based on crude drugs in medical care.

1. Accumulation of evidence

We will encourage the establishment of methods for evaluating usefulness, the scientific elucidation of shou that is the unique concept for Kampo, and medical economics research to contribute to the establishment of evidence-based medicine in Kampo treatment.
In addition, we will contribute to the healthy lives of many patients by accumulating evidence of new uses, including supportive therapy in cancer treatment and medical care for frailty in the elderly.

2. Inclusion of Kampo products and others based on crude drugs for ethical use in these practice guidelines

We contribute to expanding the range of treatment by accumulating evidence to increase formulations listed on treatment guidelines to allow many physicians to use Kampo products and others based on crude drugs.

3. Securing of safety and promotion of proper use of Kampo products and others based on crude drugs

We at JKMA will independently prepare the materials for providing information about proper use of Kampo products and others based on crude drugs and will disseminate information to healthcare facilities and general users via our website and other media. We will continue to raise the value of Kampo products and others based on crude drugs as pharmaceutical products and will establish the usefulness in healthcare.

Vision 2 We will diligently try to procure the necessary quantity of crude drugs for Kampo preparations.

1. Securing of necessary quantity of crude drugs for Kampo preparations

As for domestic cultivation, we will increase production about three times by solving many issues, for instance, securing seeds and seedlings, training cultivation technicians and instructors, founding processing/preparation facilities, and raising efficiency and ensuring continuity of production. Today, we import approximately 80% of crude drugs for Kampo preparations from China. In this context, we will try to maintain a favorable relationship with the country. In addition, we will increase sources to manage the risk of delayed procurement caused by natural calamities and abnormal weather.

2. Promotion of cultivation of crude drugs for Kampo preparations

We will conduct a survey on the ratios of cultivated forms and wild forms of crude drugs to choose preferred items and promote cultivation without limiting production areas.

3. Japan-China interchange for stable procurement of crude drugs for Kampo preparations

We are currently communicating with China and exchanging information. We will regularly interchange with China to maintain and develop a successful bilateral relationship and stably secure crude drugs for Kampo preparations.

Vision 3 We will strengthen the quality control process from crude drugs for Kampo preparations to finished products for the stable supply of quality Kampo products and others based on crude drugs.

1. Assurance of quality of crude drugs for Kampo preparations

We will enhance surveillance and research on quality, including origin, properties, verification tests, and quantitative methods of crude drugs, and train the crude drug managers who play a key role in good manufacturing practices for Kampo to upgrade the level of quality control for crude drugs comprehensively.

2. Assurance of quality in the process from crude drugs for Kampo preparations to final products, and stable supply

We will ensure thorough quality control with good manufacturing practices and voluntary standards as well as the stable supply of quality Kampo products and others based on crude drugs. Additionally, we will advocate familiarization with the JKMA version of GACP among farmers and assure quality in the safety in crude drugs for Kampo preparations, Kampo products and others based on crude drugs, for instance, controlling pesticide residue, heavy metal, and microorganisms.

3. Response to ISO/TC 249

We will respond to ISO/TC 249 appropriately and use information on other ISO technical committees effectively by offering new suggestions and submitting opinions about the activities associated with the quality of crude drugs for Kampo preparations.

4. Stable supply of Kampo products for ethical use

To continuously secure a stable supply of Kampo products and others based on crude drugs for ethical use, we will approach administrative bodies and related organizations.

Vision 4

We will expand the development of new dosage forms and research on additional indications of Kampo products for ethical use and support the establishment of guidelines for applications of pharmaceuticals containing multiple ingredients, such as Kampo products.

1. Promotion of research on Kampo products and others based on crude drugs and the establishment of guidelines for applications for pharmaceuticals containing multiple ingredients

We will promote the development of new dosage forms and research on additional indications of Kampo products for ethical use. In addition, we will support the establishment of guidelines for applications for pharmaceuticals containing multiple ingredients.

Vision 5

We will boost the development of OTC Kampo products and crude drug products and enhance post-marketing information provision.

1. Encouragement of self-medication

We will encourage self-medication through the development and fulfillment of OTC Kampo products that are made from crude drugs and crude drug products.

2. Development of OTC Kampo products and crude drug products

The environment exists for approval of Kampo products and others based on crude drugs, for example, inclusion of more formulations in standards of approval. We will continue to advocate research and development of OTC Kampo products and crude drug products.

3. Enhancement of provision of information on OTC Kampo products and crude drug products

We will enhance outreach activities for consumers by sharing actual cases of consultations with consumers and providing information and materials via lecture meetings and leaflets.

4. Advertisements of OTC Kampo products and crude drug products

We will enhance the advertising functions in cooperation with the related organizations and promote the proper use of OTC Kampo products and crude drug products.

Vision 6

We will upgrade reliability by strengthening compliance as well as quality and safety control for Kampo products and others based on crude drugs in corporate members.

1. Fortification of compliance activities

We will promote the construction and rearrangement of the compliance system and elevation of corporate ethics, and prevent corporate scandals to increase trust among people.

2. Fortification of the three-key-role system

To facilitate the execution of jobs in the three key roles as defined in the laws and regulations, we will request that corporate members fortify the three-key-role system to upgrade reliability in quality and safety control for Kampo products and others based on crude drugs.

Vision 7

We will contribute to the conservation of the global environment and biological diversity, the protection of wild plants and animals, and will proactively work toward the international expansion of crude drugs that are natural blessings.

1. Enhancement of eco-friendly activities

We will contribute to the achievement of a low carbon society, a recycling-based society, and a natural symbiosis society in consideration of global trends including the Paris Agreement and SDGs.

2. Appropriate response to international treaties including the Convention on Biological Diversity

We will observe the domestic laws of the crude drug producing countries under the principles of the Convention on Biological Diversity and the Nagoya Protocol on Access and Benefit-sharing. We will observe the domestic laws relating to endangered species in accordance with CITES.

3. Promotion of international expansion of Kampo products and others based on crude drugs

We will transmit the knowledge of Kampo products and others based on crude drugs from Japan to the world to contribute to the improvement of global public health and promote the international expansion of these products.

Vision 8

We will implement outreach activities and enhance collaboration with the related organizations, academic societies, research institutions, administrative bodies, and others.

1. Provision of information to people and fulfillment of outreach activities

We will try to popularize Kampo by providing information to effectively raise awareness. Additionally, we will fulfill outreach activities to build trust through interactive dialogues with people.

2. Enhancement of collaboration with academic societies and universities relating to crude drugs and Kampo

We will enhance collaboration with academic societies and universities related to crude drugs and will cooperate in human resource development, for example, organizing symposiums at academic meetings concerning crude drugs in the industry and proactively sending lecturers to special lectures about Kampo and crude drugs at universities.

3. Enhancement of cooperation with the related organizations, academic societies, research institutions, administrative bodies, and others

We will enhance communications with the related organizations, academic societies, research institutions, administrative bodies, and others and solve issues under satisfactory cooperation promptly and properly.

Five year action plan (FY2021 to FY2025)

Plan for the execution of the road map to realize the Future Vision for Kampo Medicines 2040

Vision 1:Further accumulation of evidence and establishment of usefulness

1.Accumulation of evidence

(1)Encourage relevant organizations to establish a research support system
(2)Accumulate high-quality evidence through research into supportive therapy in cancer treatment (for the reduction of the side effects of anticancer drugs)
(3)Promote research on Kampo medicine's usefulness in addressing physical frailty
(4)Implement subsidized projects to accelerate medical economics research
(5)Cooperate with the Committee for EBM, the Japan Society for Oriental Medicine to promote the publication of Kampo Treatment Evidence Reports (EKAT)

2.Inclusion of Kampo products and others based on crude drugs for ethical use in these practice guidelines

(1)Increase the number of guidelines including the 30 general-purpose prescriptions of Kampo products for ethical use
(2)Cooperate with the Committee for EBM, the Japan Society for Oriental Medicine to promote the publication of the Clinical Practice Guidelines For Kampo Medicine-Containing Products in Japan (KCPG).

3.Securing of safety and promotion of proper use of Kampo products and others based on crude drugs

(1)Establish a safety management system for manufacturers and distributors in response to the requirements of the Pharmaceutical and Medical Device Act, and ensure that safety management monitoring is continuously implemented.
(2)For implementing appropriate response for the notification of reevaluation results of products, establish a solid structure through which measures can be worked on throughout the year.
(3)Discuss responses to consultations and complaints concerning Kampo products
(4)Make sure that corporate members comply with the new guidelines on statements in package inserts for ethical drugs by the end of March 2024, i.e., the end of the grace period.
(5)Create and publish an updated version of the Precautions for Kampo products for ethical use standardized within JKMA, which covers the responses to new guidelines on statements .
(6)Within the two-year grace period, observe the principle to make the electronic information of the package insert, as stipulated by the amended Pharmaceutical and Medical Device Act, which was enacted on August 1, 2021.
(7)Prepare materials and provide information about proper use of Kampo products and others specifically for each stakeholder (healthcare workers, patients, general consumers, the media, and other stakeholders).
(8)Strengthen the support system for research for the safety of OTC Kampo products and the activities of the study group (MHLW grants system), resulting in the enhancement of the provision of safety information.
(9)To promote proper use, exchange information on safety and proper use both domestically and abroad.
(10)Build relationships with key opinion leaders to promote the proper use
(11)Promote corporate members' prompt and reliable responses to revisions of the Precautions of OTC Kampo products and crude drug products.
(12)Support corporate members promotional activities that contribute to proper use.

Vision 2:Continuous and stable securing of crude drugs for Kampo preparations and expansion of domestic production of crude drugs

1.Securing of necessary quantity of crude drugs for Kampo preparations

(1)Take appropriate measures to secure the required amount of crude drugs for Kampo preparations.
(2)Conduct surveys on the consumption amounts of crude drugs for Kampo preparations and other products to understand actual status of distribution and take appropriate measures.
(3)Investigate and analyze production volumes, prices, and other matters to expand the volume of domestically produced crude drugs for Kampo preparations.

2.Promotion of cultivation of crude drugs for Kampo preparations

(1)Implement measures to promote and expand the domestic production of crude drugs for Kampo preparations
(2)Conduct a survey on the production volumes of crude drugs for Kampo preparations (wild forms)and other products, and promote cultivation.

3.Japan-China interchange for stable procurement of crude drugs for Kampo preparations

(1)Exchange information at networking events through visits from and to the China Chamber of Commerce for Import & Export of Medicines & Health Products, and make the necessary efforts to achieve the stable procurement of crude drugs for Kampo preparations.
(2)Organize problem-solving-type networking events with specific themes and strengthen the foundation for the stable securing of crude drugs.

Vision 3:Upgrade quality control from crude drugs for Kampo preparations to final products, strengthen the product quality assurance system, and stably supply Kampo products for ethical use and other products

1.Assurance of quality of crude drugs for Kampo preparations

(1)Investigate the situation regarding the pesticides used in the cultivation of medicinal plants in China and respond appropriately.
(2)Investigate the situation regarding the training of people responsible for the management of crude drugs, understand the challenges, and support training.
(3)Clarify the relationship between GMP and GACP and reflect it in GMP for Kampo.

2 .Assurance of quality in the process from crude drugs for Kampo preparations to final products, and stable supply

(1)Investigate corporate members' compliance with the JKMA version of GACP and address challenges.
(2)Promote the listing of unlisted crude drugs in the Japanese Pharmacopoeia, non-JP crude drug standards, and the revision of listed crude drugs.
(3)Investigate and collect opinions about products not listed in the Japanese Pharmacopoeia and products that will be revised, and work on the preparation for for revisions.
(4)Appropriately respond to the establishment of crude drug extract specifications and study methods
(5)Improve the quality system through continuous training activities in response to notifications issued by regulatory authorities.
(6)Work to collect information on new evaluation systems for quality control, including those relating to impurities, aim to achieve advanced quality control, and strengthen the product quality assurance system.
(7)Provide guidelines by identifying the trends from the perspective of international harmonization, such as PIC/S GMP ANNEX7 and WHO GMP Guide, and take appropriate measures.

3.Response to ISO/TC 249

(1)Dispatch experts for various domestic and international ISO/TC249 activities to use the ISO standard as a foothold for international expansion. Based on proposals from each country, put together the industry's attitudes related to each committee at the International Committee Expansion Conference.And work to establish ISO standards that are advantageous to JKMA.
(2)Dispatch two industry representatives to the JLOM-sponsored chief examiner's meeting and express the industry's opinions to reflect the opinions and voting attitudes of the general public in Japan.
(3)Develop and publish new international standards related to GACP in collaboration with the China Chamber of Commerce for Import & Export of Medicines & Health Products and the Traditional Chinese Medicine Resource Center of the China Academy of Chinese Medical Sciences.
(4)Continue to develop two international standards (manufacturing method and quality of granules/GACP guidelines)led by JKMA.

4.Stably supply Kampo products for ethical use and other products

(1)Exchange opinions, negotiate, consult, and propose solutions to the Economic Affairs Division, and provide explanations to the members of the Federation of Pharmaceutical Manufacturers' Associations of Japan and the Central Social Insurance Medical Council so that Kampo products and crude drug products can be included in defined basic drugs and the number of crude drugs included in defined basic drug can be expanded.
(2)In preparation for re-examination for product unprofitability and upward price revision for Kampo products, crude drug products, and crude drugs which do not have any substitutes, analyze results, consider new countermeasures, summarize desired items, set priorities, submit calculation tables regarding the desired items (corporate members), and hold hearings.
(3)Collect and analyze information on discussions related to drug price revisions every year and respond.
(4)Prepare to set minimum drug prices for Kampo products for ethical use and other products
(5)Collect and analyze information on benefits, coverage and drug price system reforms from the Social Security Council, the Central Social Insurance Medical Council, the Council on Economic and Fiscal Policy and others, and prepare appropriate materials as necessary.

Vision 4:Promotion of research for the development of new dosage forms and additional efficacy indications for Kampo products for ethical use toward the establishment of guidelines

1.Promotion of research on Kampo products and others based on crude drugs and the establishment of guidelines for approval applications for pharmaceuticals containing multiple ingredients

(1)Cooperate in the establishment of guidelines for approval applications for pharmaceuticals (to add new dosage forms), and once guidelines are issued, promote our corporate members' product development.
(2)Cooperate in the establishment of guidelines for approval applications for pharmaceuticals(change of formulations such as change of additives).

Vision 5:Promotion of the development of OTC Kampo products and crude drug products and strengthening the information provision system

1.Encourage self-medication using OTC Kampo products

(1)Promote and review the tax system in collaboration with OTC-related organizations and promote JKMA's own promotion activities for self-medication
(2)Conduct educational activities to promote self-medication through open lectures and seminars for the public
(3)Build relationships with key opinion leaders to promote self-medication

2.Development of OTC Kampo products and crude drug products

(1)Study new attractive prescriptions and conduct literature research to review the efficacy of OTC Kampo products.
(2)Collect information from other organizations and public institutions to consider new attractive prescriptions and review the efficacy of OTC Kampo products.
(3)Promote relationships with key opinion leaders to consider new attractive prescriptions and review the efficacy of OTC Kampo products.
(4)Provide support for the publicization of attractive new prescriptions, the review of the efficacy of OTC Kampo products and the revision of approval criteria for OTC Kampo products.
(5)Promote investigation and coordination toward the establishment of approval standards for Tokisenkyu preparations to contribute to the realization of a society that includes the active participation of women.
(6)Continue searching for materials to establish approval standards for new crude drug products that contribute to extending healthy life expectancy.

3.Strengthen the information provision for and advertising of OTC Kampo products and crude drug products

(1)Consult with experts from public institutions and collect advice to strengthen outreach activities for OTC Kampo products.
(2)Provide information on the efficacy and safety of crude drug products and encourage self-regulation through the Japan Self-Medication Industry Promotion Code Committee and others.
(3)In cooperation with relevant organizations, collect and share information on the proper advertising of OTC Kampo products, crude drug products, and other products. In addition, make proposals and strengthen the feedback system within JKMA.
(4)Share information on the content published by the Advertising Review Board of the Japan Federation of Self-Medication Industries, and hold advertising workshops to ensure thorough compliance with the Standard for Adequate Advertisement of Pharmaceutical Products.(annually)
(5)Develop a website or app about Kampo products to ensure thorough compliance with the Standard for Adequate Advertisement of Pharmaceutical Products.

Vision 6:Strengthening the compliance system and improving reliability

1.Fortification of compliance activities

(1)Conduct a fact-finding survey of the compliance activities of corporate members and verify the results.
(2)Organize lectures and workshops on compliance.
(3)Encourage corporate members to establish a department or have a person in charge of compliance.
(4)Create a model for compliance-related norms
(5)Review the JKMA Code of Practice as necessary and revise it according to the situation.
(6)Thoroughly ensure that corporate members publish transparency guidelines before the deadline.
(7)Publish corporate members' transparency guidelines on the JKMA website
(8)Share the content of the report on the project for monitoring sales information provision activities and ensure that the promotional activities conducted by corporate members are appropriate.
(9)Support corporate members to establish a sales information provision activity system

2.Fortification of the three-key-role system

(1)Establish a three-key-role system that meets the requirements of the Pharmaceutical and Medical Device Act and ensure that it is put it into practice.
(2)Build a collaborative system for corporate members to take appropriate measures
(3)Continuously share the latest information and implement education, training and other activities.
(4)Comply with revisions of the regulatory systems, including the second year (2021)compliance system for the 2019 amendments to the Pharmaceutical and Medical Device Act, general exception provisions, and others.
(5)Promote the operation of appropriate quality management systems and improve reliability by strengthening cooperation between manufacturers and distributors.

Vision 7:Promotion of business activities in consideration of biodiversity and the global environment, including the conservation of the natural environment, the protection of crude drug resources and other issues, and the international expansion of Kampo products and other products based on crude drugs

1.Promotion of activities that are considerate of the global environment

(1)Follow-up with corporate members
・Conduct a fact-finding survey and understand the conditions of corporate members' environmental activities
・Increase the number of organizations which are participating in the achievement of the FPMAJ's goals and solicit participation in the environment subcommittee
・Share information, including the results of activities to achieve the FPMAJ's goals and environment-related seminars organized by the FPMAJ
(2)Contribution to the realization of the action plan for low carbon society (CO2)
・Achieve the goal of reducing carbon dioxide emissions by 25% compared to FY2013 by 2030
(3)Contribution to the realization of a plan for the establishment of a recycling-based society (waste)
・Work toward a 75% reduction of final disposal of industrial waste by FY2025 compared with the amount in FY2000, and an increase the percentage of waste recycled to 60% or more.
・Work toward increasing the percentage of waste plastic recycled to 65% or more by FY2030.

2.Appropriate response to international treaties including the Convention on Biological Diversity

(1)Comply with laws and treaties on the conservation of endangered wild animal and plant species both in Japan and overseas, and procure necessary crude drugs.
(2)In the event of a situation that affects the stability of supply, address the situation in cooperation with the FPMAJ Washington Convention Liaison Committee.
(3)Comply with the domestic laws of crude drug exporting countries and respond appropriately based on the Convention on Biological Diversity

3.Promotion of international expansion of Kampo products and others based on crude drugs

Review and revise the JKMA version of GACP with a view toward ISO standards

Vision 8:Strengthening industry-government-academia collaboration and enhancing outreach activities

1.Provision of information to people and fulfillment of outreach activities

(1)Organize open lectures for the public that are responsive to the new normal created by the COVID-19 pandemic, while building a system for public hearings.
(2)Work on the implementation of a new outreach strategy based on the Survey on Awareness and Experiences of Kampo products summarized in FY2020. Regularly verify results through awareness surveys and continuously engage in public relations activities to meet the needs of the times.
(3)Examine and verify means of sharing information in line with the times so that a standardized system which enables effective, efficient and continuous information transmission can be constructed.
(4)Promote the strengthening and specialization of public relations functions to share information related to JKMA's activities in ways that develop support and the understanding of internal and external stakeholders.
(5)Build an efficient information sharing system within JKMA so that information can be disseminated externally and provided to corporate members in a more timely manner in order to further promote understanding of JKMA's activities both internally and externally .
(6)When holding a open seminar on Kampo medicine, examine and verify both the software and hardware that will be used according to the current social environment, and effectively organize the seminar with optimal content in an appropriate way.
(7)Promote the marketability of OTC Kampo products and crude drug products according to their applicable scopes and product characteristics and advertise them at public relations opportunities.
(8)Investigate and examine people's awareness and usage of Kampo products and other products based on crude drugs for ethical use.

2.Enhancement of collaboration with academic societies and universities relating to crude drugs and Kampo medicines

(1)Incorporate the content and recommendations of the Forum: The Vision for Kampo Medicines and Public Welfare in line with the times (infectious diseases, topics, etc.), and hold the Forum to increase the awareness that relevant organizations, academic societies, research institutes, governments, and others have of the role of Kampo medicine, which plays a role in people's health and medical care.
(2)Organize symposiums and other events based on the results of the forum, The Vision for Kampo Medicines and Public Welfare.
(3)Cooperate with the Japan Society for Oriental Medicine to organize a symposium at the academic general meeting and share evidence on recommended items.
(4)For the six proposals of the Forum: The Vision for Kampo Medicines and Public Welfare, understand their progress in cooperation with the relevant committees, and regularly share information with the members of the Forum and relevant organizations.
(5)Enhance collaboration with academic societies and universities relating to crude drugs and Kampo
(6)Identify and address issues related to the regulation of OTC Kampo products together with other organizations.

3.Enhancement of cooperation with the related organizations, academic societies, research institutions, administrative bodies, and others

(1)Assign official administrative officers in charge of Kampo medicine in collaboration with academic societies and other organizations.
(2)Exchange opinions with the Japan Society for Oriental Medicine on the ideal ways to promote the activities of corporate members
(3)Regularly report the results of the examination of outline of product information to the Ministry of Health, Labour and Welfare.
(4)Through the development of approval standards for new crude drug products, such as Tokisenkyu preparations, expand cooperation with academia, research institutes, governments, and others.

Business plan for FY2022 (Developed in May 2022)

On the Establishment of the Business Plan

We will promote more activities in accordance with the road map and five year action plan to realize the Future Vision for Kampo Medicines 2040 - Responsibility for People's Health and Healthcare -.

In the second year of the first five year action plan for realization of the Future Vision for Kampo Medicines 2040, we will actively promote activities aimed at solving issues and also push ahead without delay with preparations to celebrate the 40th anniversary of our foundation in 2023.

JKMA will promote the further accumulation of evidence for Kampo products and other products based on crude drugs and establish their usefulness.

We are launching a medical economics research grant project for Kampo products and other products based on crude drugs to encourage medical economics research into areas where Kampo medicines are expected to be effective such as geriatric diseases and supportive care in cancer. This will enable us to contribute to the advancement of Kampo medicines through identification of those conducting research into the medical economics of Kampo products and other products based on crude drugs, and expansion in the scope of research domains. It will also help accelerate the accumulation of evidence through the publication of research findings at the Forum: The Vision for Kampo Medicines and Public Welfare, meetings of influential medical associations and in scientific literature.

JKMA will work to promote and expand the cultivation of domestically produced crude drugs to ensure a stable supply of crude drugs for Kampo preparations.

The development of good relations with China is a prerequisite for securing the necessary volume of crude drugs for Kampo preparations. We will continue to build good relations by creating opportunities for Japan-China exchange with the China Chamber of Commerce for Import & Export of Medicines & Health Products and for the online exchange of opinions and information. Meanwhile, to ensure a continuous and stable supply of crude drugs for Kampo preparations, wherever possible, efforts to develop multiple production areas from which to source crude drugs are needed. As a project to strengthen the framework for regional specialty crops such as tea and medicinal crops funded by the Ministry of Agriculture, Forestry and Fisheries to expand the production volume of domestically produced crude drugs, we will continue to hold in-person and online briefing and consultation sessions to develop production areas for medicinal crops in Japan in cooperation with the Ministry of Agriculture, Forestry and Fisheries, the Ministry of Health, Labour and Welfare and other agencies, and will ensure a stable supply of high quality crude drugs for Kampo preparations.

JKMA will strive for the assurance of quality in the process from crude drugs for Kampo preparations to final products, and stable supply.

To improve the quality of the crude drugs for Kampo preparations, we will promote enhancement of the content of standards including proposing listing in JP and non-JP crude drug standards. Meanwhile, in response to administrative notices such as "Thorough strengthening of legal compliance framework and manufacturing control framework at drug marketing authorization holders and manufacturers," we will seek to update knowledge and increase understanding about products and manufacturing processes by holding seminars and PQS/QRM workshops for executives and those in charge and, by strengthening the Kampo GMP framework, we will thoroughly implement quality control and maintain a stable supply of high quality Kampo products and other products based on crude drugs.

JKMA will promote the utilization of OTC Kampo products and crude drug products in the self-medication domain.

The self-medication taxation system originally introduced as a time-limited taxation system for five years from 2017 will now be extended for a further period of five years from 2022. Previously only OTC ingredients on the Rx-to-OTC switch list qualified for the system but now 42 ingredients not on the Rx-to-OTC switch list will also qualify. Also among OTC Kampo products/crude drug products, many products that contain the three crude drugs Ephedra, Lumbricalis and Nandian Fruit are now covered by the system. We will continue supporting calls for revisions such as making the taxation system permanent and making all OTC drugs qualify for the system, and we will also keep up awareness raising activities to make Kampo and crude drug products more readily available to the Japanese public, including providing information to improve the rate of utilization.

JKMA will strengthen its own compliance framework and that of member companies.

The results of analysis of a questionnaire on the status of compliance initiatives conducted last year show clear improvement from the previous survey in areas such as the development of hotlines and clarification of where responsibility lies. However, it is deeply regrettable that there is no sign of improvement in areas such as the creation of manuals and the implementation of awareness surveys. To continue to maintain a stable supply of Kampo products and other products based on crude drugs, we will not only support and cooperate with compliance initiatives but will also pay utmost attention to further improvement of compliance awareness and the development of a compliance framework at member companies.

Recently, there has been a spate of quality violations in the pharmaceutical industry and there have been times when the fallout from such violations such as the suspension of operations has caused supply instability. Unfortunately, similar violations that could undermine trust in Kampo products and other products based on crude drugs have occurred at some of our member companies. The development of a compliance framework was previously a voluntary endeavor but now that it is mandatory for all companies regardless of size under the revised Pharmaceuticals and Medical Devices Act, there is no excuse. JKMA provides appropriate guidance and useful information to its member companies and holds regular study meetings for them, in the hope that the senior executives that represent member companies demonstrate a policy of compliance to all their employees. JKMA and its member companies will once again take stock of this situation and have a sense of urgency about improving these issues and we will also push ahead with activities to strengthen the compliance framework of member companies.

In FY2022, JKMA will continue to contribute to Japanese public health and the advancement of the pharmaceutical industry by forging close cooperation among its member companies, to maintain a stable supply of high quality Kampo products and other products based on crude drugs and to ensure their safety and proper use.

FY2022 JKMA's Business Policy

I.Further accumulation of evidence and establishment of usefulness

1.Accumulation of evidence

(1)Continue and expand the Kampo medicine-related subsidy projects by working with relevant organizations to establish a research support system.
(2)Promote research for therapies supporting cancer treatment (to reduce the side effects of anticancer drugs).
(3)Promote research for the usefulness of Kampo medicine to address physical frailty.
(4)Implement subsidized projects to accelerate medical economics research
(5)Cooperate with the Committee for EBM, the Japan Society for Oriental Medicine to promote the publication of Kampo Treatment Evidence Reports (EKAT)

2.Inclusion of Kampo products and others based on crude drugs for ethical use in these practice guidelines

(1)For the thirty general prescriptions of Kampo products, aim to expand the number of guidelines for diseases with high medical needs.
(2)Cooperate with the Committee for EBM, the Japan Society for Oriental Medicine to promote the publication of the Clinical Practice Guidelines For Kampo Medicine-Containing Products in Japan (KCPG).

3.Securing of safety and promotion of proper use of Kampo products and others based on crude drugs

(1)Establish a safety management system for manufacturers and distributors in response to the requirements of the Pharmaceutical and Medical Device Act, and ensure that safety management monitoring is continuously implemented.
(2)For implementing appropriate response for the notification of reevaluation results of products, establish a solid structure through which measures can be worked on throughout the year.
(3)Discuss responses to consultation and complaints concerning Kampo products
(4)Make sure that the corporate members comply with the new guidelines regarding statements on package inserts by the end of March 2024, i.e., the end of the grace period.
(5)Within the two-year grace period, observe the principle to make the electronic information of the package insert, as stipulated by the amended Pharmaceutical and Medical Device Act, which was enacted on August 1, 2021.
(6)Prepare materials and provide information about the proper use of Kampo products and other products based on crude drugs specifically for each stakeholder (healthcare workers, patients, general consumers, the media, and other stakeholders).
(7)Strengthen the support system for research into the safety of OTC Kampo products and the activities of the study group, resulting in the enhancement of the provision of safety information.
(8)To promote the proper use, exchange information on safety and proper use both domestically and abroad.
(9)Promote corporate members' prompt and reliable responses to revisions of the Precautions regarding OTC Kampo products and crude drug products.
(10)Support corporate members' promotional activities that contribute to proper use.

II.Continuous and stable securing of crude drugs for Kampo preparations and expansion of domestic production of crude drugs

1.Securing of necessary quantity of crude drugs for Kampo preparations

(1)Take appropriate measures to secure the required amount of crude drugs for Kampo preparations
(2)Conduct surveys on the consumption amounts of crude drugs for Kampo preparations and others to understand actual status of distribution and take appropriate measures

2.Promotion of the cultivation of crude drugs for Kampo preparations

(1)Implement measures to promote and expand the domestic production of crude drugs for Kampo preparations
(2)Conduct a survey on the production volumes of crude drugs for Kampo preparations (wild forms) and other products, and promote cultivation

3.Japan-China interchange for stable procurement of crude drugs for Kampo preparations

Exchange information at networking events through visits to and from the China Chamber of Commerce for Import & Export of Medicines & Health Products, and the make necessary efforts to achieve the stable procurement of crude drugs for Kampo preparations

III.Upgrade quality control from crude drugs for Kampo preparations to final products, strengthen the product quality assurance system, and stably supply Kampo products for ethical use and other products

1.Assurance of quality of crude drugs for Kampo preparations

(1)Investigate the situation regarding the pesticides used in the cultivation of medicinal plants in China and respond appropriately.
(2)Investigate the situation regarding the training of people responsible for the management of crude drugs, understand the challenges, and support training.
(3)Clarify the relationship between GMP and GACP and reflect it in GMP for Kampo.

2 .Assurance of quality in the process from crude drugs for Kampo preparations to final products, and stable supply

(1)Investigate corporate members' compliance with the JKMA version of GACP and address challenges.
(2)Propose the listing of unlisted crude drugs in the Japanese Pharmacopoeia and non-JP crude drug standards and promote the revision of listed crude drugs.
(3)Investigate and collect opinions about products not listed in the Japanese Pharmacopoeia and products that will be revised, and work on the preparation for for revisions.
(4)Appropriately respond to the establishment of crude drug extract specifications and study methods
(5)Improve the quality system through continuous training activities in response to notifications issued by regulatory authorities.
(6)Work to collect information on new evaluation systems for quality control, including as they relate to impurities, aim to advanced quality control, and strengthen the product quality assurance system.
(7)Provide guidelines by identifying trends from the perspective of international harmonization, such as PIC/S GMP ANNEX7 and WHO GMP Guide, and take appropriate measures.

3.Response to ISO/TC 249

(1)Dispatch experts for various domestic and international ISO/TC249 activities to use the ISO standard as a foothold for international expansion. Based on proposals from each country, put together the industry's attitudes related to each committee at the International Committee Expansion Conference, and work to establish ISO standards that are advantageous to JKMA.
(2)Dispatch two industry representatives to the JLOM-sponsored chief examiner's meeting and express the industry's opinions to reflect the opinions and voting attitudes of the general public in Japan.
(3)Develop and publish new international standards related to GACP in collaboration with the China Chamber of Commerce for Import & Export of Medicines & Health Products and the Traditional Chinese Medicine Resource Center of China Academy of Chinese Medical Sciences.
(4)Continue to develop two international standards (manufacturing method and quality of granules/GACP guidelines) led by JKMA.

4.Stable supply of Kampo products for ethical use and other products

(1)Exchange opinions, negotiate, consult, and propose solutions to the Economic Affairs Division, and provide explanation to the members of the Federation of Pharmaceutical Manufacturers' Associations of JAPAN and the Central Social Insurance Medical Council so that Kampo products and crude drug products can be included in defined basic drugs and the number of crude drugs included in defined basic drugs can be expanded.
(2)In preparation for a re-examination of product unprofitability and upward price revision for Kampo products, crude drug products, and crude drugs which do not have any substitutes, analyze the results, consider new countermeasures, summarize desired items, set priorities, submit calculation tables regarding the desired items (corporate members), and hold hearings.
(3)Collect and analyze information on discussions related to drug price revisions every year and respond.
(4)Collect and analyze information on benefits, coverage and drug price system reforms from the Social Security Council, the Central Social Insurance Medical Council, the Council on Economic and Fiscal Policy and others, and prepare appropriate materials as necessary.

IV.Promotion of research for the development of new dosage forms and additional efficacy indications for Kampo products for ethical use toward the establishment of guide lines

1.Promotion of research on Kampo products and others based on crude drugs and the establishment of guidelines for applications for pharmaceuticals containing multiple ingredients

(1)Raise awareness of the approval application guidelines (addition of formulations with different dosage forms) published in July 2021 and encourage product development by member companies.
(2)Cooperate in the establishment of guidelines for approval applications for pharmaceuticals (changes of formulations such as changes of additives).

V.Promotion of the development of OTC Kampo products and crude drug products and strengthening the information provision system

1.Encourage self-medication using OTC Kampo products

(1)Promote and review the tax system in collaboration with OTC-related organizations and promote JKMA's own promotion activities for self-medication
(2)Conduct educational activities to promote self-medication through open lectures and seminars for the public
(3)Build relationships with key opinion leaders to promote self-medication

2.Development of OTC Kampo products and crude drug products

(1)Study for new attractive prescriptions and conduct literature research to review the efficacy of OTC Kampo products.
(2)Promote investigation and coordination toward the establishment of approval standards for Tokisenkyu preparations to contribute to the realization of a society that includes the active participation of women.

3.Strengthen the information provision for and advertising of OTC Kampo products and crude drug products

(1)Consult with experts from public institutions and collect advice to strengthen outreach activities for OTC Kampo products.
(2)Provide information on the efficacy and safety of crude drug products and encourage self-regulation through the Japan Self-Medication Industry, Promotion Code Committee and other organizations.
(3)In cooperation with relevant organizations, collect and share information on the proper advertising of OTC Kampo products, crude drug products, and other products. In addition, make proposals and strengthen the feedback system within JKMA.
(4)Share information on the content published by the Advertising Review Board of the Japan Federation of Self-Medication Industries, and hold advertising workshops to ensure thorough compliance with the Standard for Adequate Advertisement of Pharmaceutical Products.

VI.Strengthening the compliance system and improving reliability

1.Fortification of compliance activities

(1)Conduct a fact-finding survey of the compliance activities of corporate members and verify the results.
(2)Organize lectures and workshops on compliance.
(3)Encourage corporate members to establish a department or have a person in charge of compliance.
(4)Thoroughly ensure that corporate members publish transparency guidelines before the deadline.
(5)Share the content of the report on the monitoring of activities providing sales information and support corporate members to establish a system for activities providing sales information.

2.Fortification of the three-key-role system

(1)Establish a three-key-role system that meets the requirements of the Pharmaceutical and Medical Device Act and ensure that it is put into practice.
(2)Build a collaborative system for corporate members to take appropriate measures
(3)Continuously share the latest information and implement education, training and other activities.
(4)Comply with revisions of the regulatory systems, including the second year (2021) compliance system for the 2019 amendments to the Pharmaceutical and Medical Device Act, general exception provisions, and others.
(5)Promote the operation of appropriate quality management systems and improve reliability by strengthening cooperation between manufacturers and distributors.

VII.Promotion of business activities that are considerate of biodiversity and the global environment, including the conservation of the natural environment, the protection of crude drug resources and other issues, and the international expansion of Kampo products and other products based on crude drugs

1.Enhancement of eco-friendly activities

(1)Conduct a fact-finding survey and understand the conditions of corporate members' environmental activities
(2)Achieve the goal of reducing carbon dioxide emissions 25% compared to FY2013 by FY2030.
(3)Work toward a 75% reduction of final disposal of industrial waste by FY2025 compared with the amount in FY2000, and an increase the percentage of waste recycled to 60% or more.
(4)Work toward increasing the percentage of waste plastic recycled to 65% or more by FY2030.

2.Appropriate response to international treaties including the Convention on Biological Diversity

(1)Comply with laws and treaties on the conservation of endangered wild animal and plant species both in Japan and overseas, and procure necessary crude drugs.
(2)In the event of a situation that affects the stable supply, address the situation in cooperation with the FPMAJ Washington Convention-related Liaison Committee.
(3)Comply with the domestic laws of crude drug exporting countries and respond appropriately based on the Convention on Biological Diversity

3.Promotion of international expansion of Kampo products and others based on crude drugs

(1)Review and revise the JKMA version of GACP with a view toward ISO standards

VIII.Strengthening industry-government-academia collaboration and enhancing outreach activities

1.Provision of information to people and fulfillment of outreach activities

(1)Develop public relations activities based on the new outreach strategy developed from the results of the survey of people's awareness of and experiences with Kampo products.
(2)Examine and verify means of sharing information in line with the times so that a standardized system which enables effective, efficient and continuous information transmission can be constructed.
(3)Promote committee activities with an awareness of the need to strength and increase the specialization of public relations functions.
(4)Lectures on the right themes at the right times in consideration of measures to acquire more viewers, based on the results of the online open lecture on Kampo medicine which was held for the first time via YouTube in FY 2020.

2.Enhancement of collaboration with academic societies and universities relating to crude drugs and Kampo

(1)Incorporate the content and recommendations of the Forum: The Vision for Kampo Medicines and Public Welfare in line with the times (infectious diseases, topics, etc.), and hold the Forum to increase the awareness that relevant organizations, academic societies, research institutes, governments, and others have of the role of Kampo medicine, which plays a role in people's health and medical care.
(2)Cooperate with the Japan Society for Oriental Medicine to organize a symposium at the academic general meeting and share evidence on recommended items.
(3)For proposals of the Forum: The Vision for Kampo Medicines and Public Welfare, understand their progress in cooperation with the relevant committees, and regularly share information with the members of the Forum and relevant organizations.
(4)Enhance collaboration with academic societies and universities relating to crude drugs and Kampo medicine.

3.Enhancement of cooperation with the related organizations, academic societies, research institutions, administrative bodies, and others

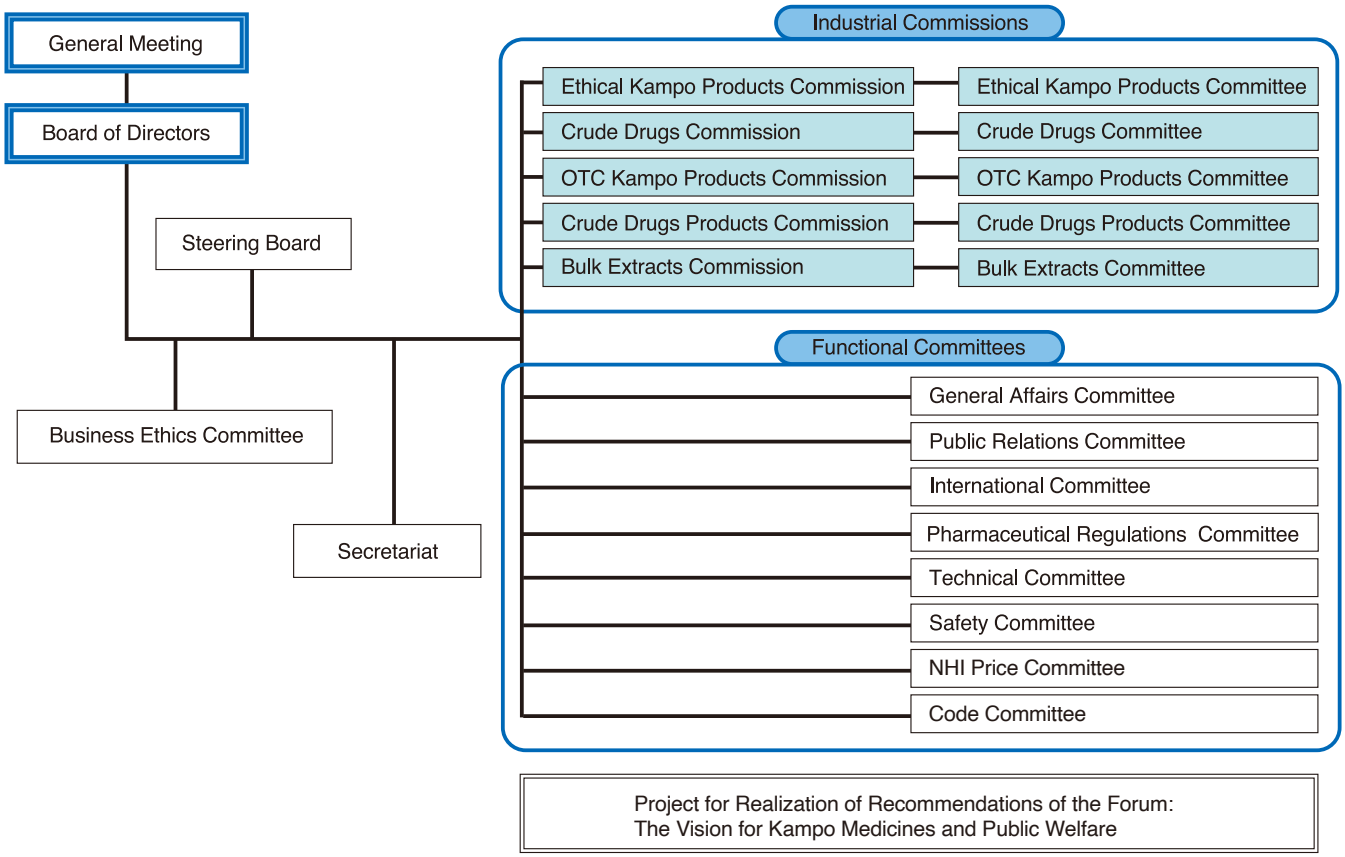
(1)Collaborate with the Japan Society for Oriental Medicine to achieve the assignment of official administrative officers related to Kampo medicine.
(2)Report the results of the examination of the outline of product information to the Ministry of Health, Labour and Welfare.
(3)Through the development of approval standards for new crude drug products, such as Tokisenkyu preparations, expand cooperation with academia, research institutes, governments, and others.

Roles of industrial commissions, projects, and functional committees

Common matters

1. Matters relating to corporate ethics
2. Matters relating to cooperation with, negotiations with, and information collection from administrative bodies and related organizations
3. Matters relating to business plans and business reports
4. Matters relating to budget

Organization of JKMA



Ethical Kampo Products Commission

Ethical Kampo Products Commission consists of 11 member companies handling ethical Kampo formulation and its bulk extracts.

Chairman
Terukazu Kato,
Tsumura & Co.

Ethical Kampo Products Committee
Chairman
Hisashi Hasegawa,
Tsumura & Co.

1. Nurturing of Kampo products for ethical use and crude drug products
2. Matters relating to adherence to fair competition rules and disclosure of Transparency Guidelines
3. Matters relating to improvement of distribution
4. Matters relating to general training of medical representatives (MRs)
5. Matters relating to usefulness of Kampo products for ethical use, such as accumulation of evidence

Crude Drugs Commission

Crude Drugs Commission consists of 28 member companies handling raw materials for crude drug (captive consumption, sales), and companies handling crude drug for dispensing and other final products.

Chairman
Daisuke Tochimoto,
Tochimoto Tenkaido Co., Ltd.

Crude Drugs Committee
Chairman
Yutaka Yamamoto,
Tochimoto Tenkaido Co., Ltd.

1. Matters relating to quality of crude drugs
2. Matters relating to distribution of crude drugs, such as survey on actual distribution of crude drugs for Kampo preparations
3. Matters relating to cultivation of crude drugs inside and outside Japan
4. Matters relating to revision of Japanese Pharmacopoeia and non-JP crude drug standards in connection with crude drugs
5. Matters relating to safety of crude drugs in China, such as survey on use of pesticides
6. Matters relating to CITES

OTC Kampo Products Commission

OTC Kampo Products Commission consists of 34 member companies handling OTC Kampo formulation.

Chairman
Tetsuya Kusayanagi,
Kracie Pharmaceutical, Ltd.

OTC Kampo Products Committee
Chairman
Ryuuji Takahashi,
Kracie Pharmaceutical, Ltd.

1. Matters relating to provision of information on OTC Kampo products to consumers
2. Matters relating to standards for approving OCT Kampo product formulations
3. Matters relating to training activities for OTC Kampo products
4. Matters relating to promotion of proper use of OTC Kampo products
5. Matters relating to cooperation on information provision and survey/research on usefulness of OTC Kampo products

Crude Drug Products Commission

Crude Drug Products Commission consists of 24 member companies handling crude drug formulation.

Chairman
Kazumasa Kobayashi,
Kobayashi Pharmaceutical Co., Ltd.

Crude Drug Products Committee
Chairman
Atsunori Wada,
Kobayashi Pharmaceutical Co., Ltd.

1. Matters relating to promotion of development and quality assurance of crude drug products
2. Matters relating to information provision and promotion of proper use of crude drug products
3. Matters relating to cooperation with the groups and organizations associated with crude drug products

Bulk Extracts Commission

Bulk Extracts Commission consists of 7 member companies manufacturing all types of extracts such as tinctures, dry extracts and so on.

Chairman
Shoichi Kuwano,
Nippon Funmatsu Yakuhin Co., Ltd.

Bulk Extracts Committee
Chairman
Hiroshi Sasaki,
Nippon Funmatsu Yakuhin Co., Ltd.

1. Matters relating to inclusion of Kampo formulations and extracts in official compendiums
2. Matters concerning the solvent for manufacturing the crude drug extract
3. Matters relating to quality of crude drug extracts
4. Matters relating to drug affairs, laws, and regulations concerning crude drug extracts

Future Vision Project for Kampo Medicines and Public Welfare

Project Leader
Kenji Ajioka,
Tsumura & Co.

1. Matters relating to cross-cutting)/sustainable development of industrial commissions and functional committees in connection with Kampo products, crude drug products, and crude drugs
2. Matters relating to realization of recommendations by Forum: The Vision for Kampo Medicine and Public Welfare

General Affairs Committee

Chairman
Satoshi Nagano,
Tsumura & Co.

1. Matters relating to business policies, business plans, and business reports
2. Matters relating to management of budget, account settlement and others
3. Matters relating to efficient operation of JKMA activities
4. Matters relating to promotion of admission of new members
5. Matters relating to compliance
6. Matters relating to lecture meetings
7. Matters relating to production of Kampo products and others based on crude drugs
8. Matters relating to environmental practice
9. Cooperation with the related organizations

Public Relations Committee

Chairman
Ritsuko Inukai,
Tsumura & Co.

1. Matters relating to PR for JKMA activities
2. Matters relating to educational activities concerning Kampo products and crude drugs
3. Matters relating to handling of inquires and interviews by news organizations and the like
4. Matters relating to handling of inquires by general consumers, medical professionals and governments
5. Matters relating to maintenance and administration of websites

International Committee

Chairman
Hirokazu Koyanagi,
Tsumura & Co.

1. Matters relating to international exchange concerning Kampo products and crude drugs
2. Matters relating to discussion on responses to changes in international situations and sharing of discussion results in connection with Kampo products and crude drugs
3. Matters relating to cooperation in the organizations associated with international issues concerning Kampo products and crude drugs

Pharmaceutical Regulations Committee

Chairman
Hirokazu Kurita,
Kracie Pharmaceutical, Ltd.

1. Matters relating to pharmaceutical affairs systems
2. Matters relating to surveys and research on the laws, regulations, and notifications associated with Kampo products and crude drug products

Technical Committee

Chairman
Yasuhiro Takasugi,
Tsumura & Co.

1. Matters relating to quality of pharmaceutical products and raw materials
2. Matters relating to listing on Japanese Pharmacopoeia and non-JP crude drug standards
3. Matters relating to impurities
4. Matters relating to GQP/GMP for pharmaceutical products
5. Matters relating to quality in international harmonization (PIC/S, FHH, ICH, and others)

Safety Committee

Chairman
Masanori Katori,
Tsumura & Co.

1. Prompt and thorough execution of safety measures such as revisions of the precautions standardized within JKMA
2. Securing of safety and promotion of proper use of Kampo products and crude drug products
3. Sharing and discussion of a variety of safety information (general situations and academic information)
4. Mutual training among members (lecture meetings and study meetings)
5. Cooperation and submission of opinions with administrative bodies and other organizations in the pharmaceutical industry
6. Responses to notifications on new points on statements in package inserts for ethical drugs
7. Appropriate responses to messages concerning reevaluation results of Kampo products for ethical use
8. Discussion on responses to consultation and complaints concerning Kampo products and others based on crude drugs

Code Committee

Code Review Board consists of 5 member companies participating in the Ethical Kampo Products Commission and the Crude Drugs Commission, in order to implement the Promotion Code for ethical Kampo formulation and crude drug.

Representative Member
Hiroyuki Matsuzuka,
Kracie Pharmaceutical, Ltd.

1. Matters relating to codes
   (1) Familiarization with Code of Practice
   (2) Promotion of improvement in promotional activities under guidelines for sales information provision
2. Matters relating to examination of outline of product information and others
   (1) Examination of outline of product information and others and feedback on examination results
   (2) Thoroughly disseminate the points to be noted when creating product information outlines and other materials to corporate members.
   (3) Reporting of opinions to and exchange of opinions with administrative bodies, etc.
3. Matters relating to Standard for Adequate Advertisement of Pharmaceutical Products

NHI Price Committee

The purpose of the NHI Pricing Committee is to contribute to the improvement of national medical care by ensuring the sustainable growth of ethical kampo formulations and crude drugs within systems such as medical insurance and the NHI drug price standard. The NHI Pricing Committee consists of 15 member companies.

Chairman
Makoto Sakaue,
Tsumura & Co.

1. Matters relating to survey/research, proposals, and countermeasures in connection with medical insurance systems and drug price standard systems
2. Matters relating to cooperation with FPMAJ medical insurance and drug price research council and information collection
3. Matters relating to holding of lecture meetings, study meetings, and others

Member Companies

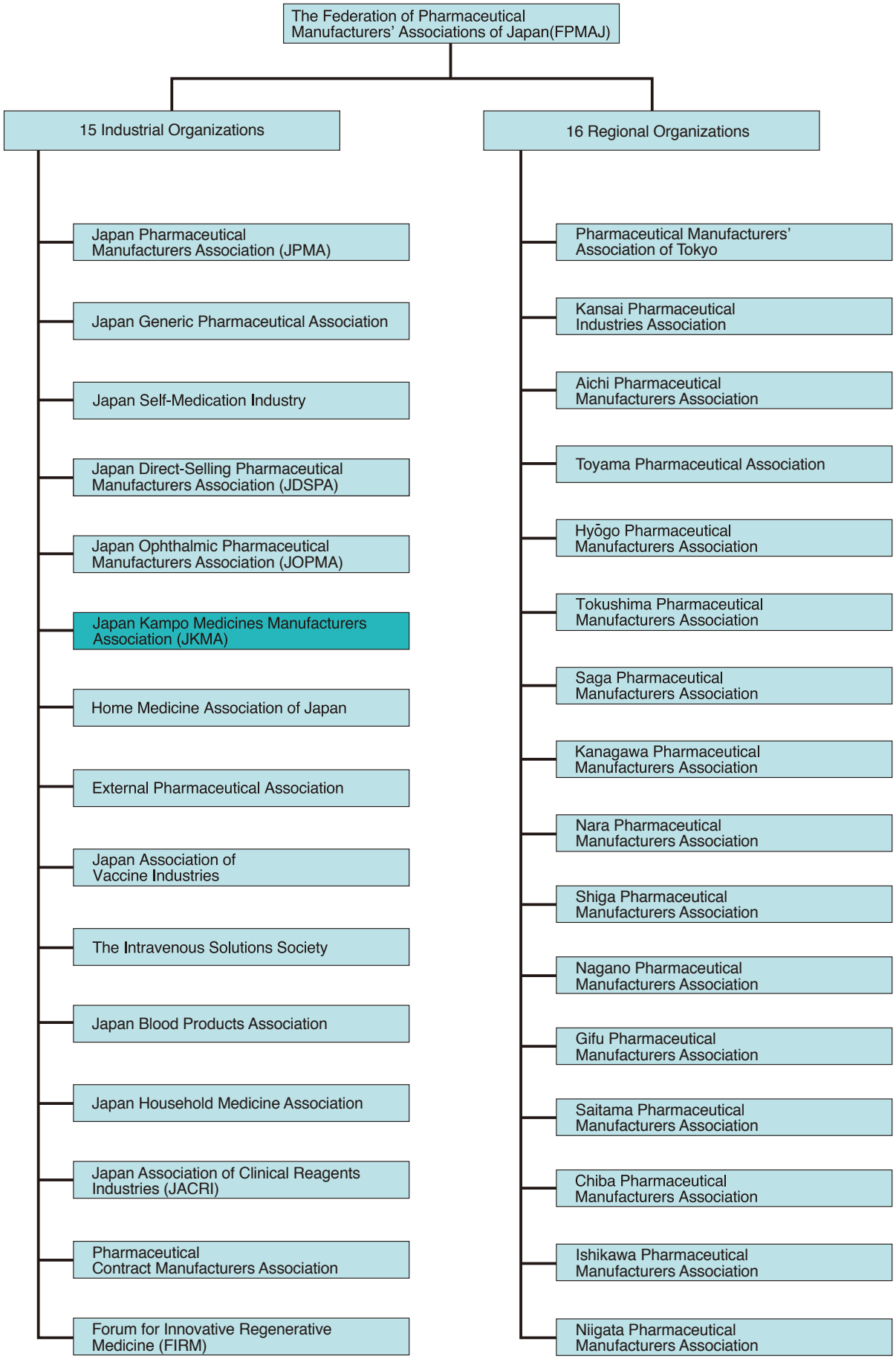
Company	Address
Alinamin Pharmaceutical Co., Ltd.	1-8-2 Marunouchi, Chiyoda-ku, Tokyo 100-0005
Alps Pharmaceutical Ind. Co., Ltd.	2-10-50 Mukai-machi, Furukawa-cho, Hida-city, Gifu 509-4241
Amari Soice Co., Ltd.	13-295 Sinmachi, Husimi-ku, Kyoto 612-8081
Asgen Pharmaceutical Co., Ltd.	2008 Azakobora, Yamada-cho, Mizunami-shi, Gifu 509-6104
Co. Sugihara Tatuji Shoten	2-7-10 Kameido, Koto-ku, Tokyo 136-0071
Daiichi Sankyo Healthcare Co., Ltd.	3-14-10 Nihonbashi-cho, Chuo-ku, Tokyo 103-8234
Daiko Shoyaku Co., Ltd.	1-5-12 Shoken, Chikusa-ku, Nagoya 464-0084
Fukudaryu Co., Ltd.	1-51-11, Nishitemma, Kita-ku, Osaka 530-0047
Hino Pharmaceutical Co., Ltd.	2-3-15 Doshomachi, Chuo-ku, Osaka 541-0045
Honzo Pharmaceutical Co., Ltd.	125 Furukawa-cho, Tenpaku-ku, Nagoya 468-0046
Ichigen Pharmaceutical Co., Ltd.	3-4-10 Kaname-cho, Toshima-ku, Tokyo 171-0043
Iskra Industry Co., Ltd.	1-14-2 Nihonbashi, Chuo-ku, Tokyo 103-0027
JPS Pharmaceutical Co., Ltd.	4-42-22 Higashiyamata, Tsuzuki-ku, Yokohama 224-0023
Kenso-Seiyaku Co., Ltd.	9-17, Nihonbasi-kobunecho, Chuo-ku, Tokyo 103-0024
Kitanihon Pharmaceutical Co., Ltd.	55 Wakasugi, Kamiichimachi, Nakaniikawa-gun, Toyama 930-0314
Kobayashi Pharmaceutical Co., Ltd.	4-4-10 Doshomachi, Chou-ku, Osaka 541-0045
KOHKAN Pharmaceutical Institute Co., Ltd.	2-1-3, Higashikanda, Chiyoda-ku, Tokyo 101-0031
Konishi Pharmaceutical Co., Ltd.	2-33-11 Kamiishikiri-cho, Higashiosaka-city, Osaka 579-8012
Kotaro Pharmaceutical Co., Ltd.	2-5-23 Nakatsu, Kita-ku, Osaka 531-0071
Kowa Company. Ltd.	4-14 Nihonbashi-honcho 3chome, Chuo-ku, Tokyo 103-0023
Kracie Pharmaceutical Co., Ltd.	3-20-20 Kaigan, Minato-ku, Tokyo 108-8080
Kyushin Pharmaceutical Co., Ltd.	1-21-7 Wada, Suginami-ku, Tokyo 166-8533
Matsuura Yakugyo Co., Ltd.	24-21 Enjo-cho, Showa-ku, Nagoya 466-0054
Melsmon Pharmaceutical Co., Ltd.	2-35-6 Higashiryouke, Kawaguchi-city, Saitama 332-0003
Mikuni & Co., Ltd.	2-4-10 Doshomachi, Chuo-ku, Osaka 541-0045
Naganoken Materia Medica Co., Ltd.	879-2 Onbegawa, Sinonoi, Nagano-city, Nagano 388-8006
Naganoken Pharmaceutical Co., Ltd.	100-1 Outakimura, Kiso-gun, Nagano 397-0201
Nippon Funmatsu Yakuhin Co., Ltd.	2-5-11 Doshomachi, Chuo-ku, Osaka 541-0045
Nippon Shinyaku Co., Ltd.	14 Nishinoshomonguchi-cho, Kisshoin, Minami-ku, Kyoto 601-8550
Nitto Pharmaceutical Industries, Ltd.	35-3 Minamibiraki, Kamiueno-cho, Muko, Kyoto 617-0006
Ohki Pharmaceutical Co., Ltd.	3-3 Kandakaji-cho, Chiyoda-ku, Tokyo 101-0045
Ohkusa Pharmaceutical Co., Ltd.	1-17-15 Morisaki, Yokosuka, Kanagawa 238-0023

Member Companies

Company	Address
Ohsugi Pharmaceutical Co., Ltd.	1-1-2 Tennoji-cho, Minami, Abeno-ku, Osaka 545-0002
Ohta′s Isan Co., Ltd.	2-3-2 Sengoku, Bunkyo-ku, Tokyo 112-0011
Ominedo Pharmaceutical Co., Ltd.	574 Nenarigaki, Yamatotakada-city, Nara 635-0051
Rohto Pharmaceutical Co., Ltd.	1-8-1 Tatsuminishi, Ikuno-ku, Osaka 544-8666
Ryukakusan Co., Ltd.	2-5-12 Higashikanda, Chiyoda-ku, Tokyo 101-0031
Sakamoto Kampow Pharmaceutical Inc.	1-5-12 Meishin-cho, Amagasaki-city, Hyogo 661-0021
Sampo Pharmaceutical Co., Ltd.	2-3-18 Shimoochiai, Shinjuku-ku, Tokyo 161-8541
Sanwa Shoyaku Co., Ltd.	6-1 Hiraide-Kogyo-Danchi, Utsunomiya-city, Tochigi 321-0905
Sato Pharmaceutical Co., Ltd.	1-5-27 Motoakasaka, Minato-ku, Tokyo 107-0051
Shinihonseiyaku Co., Ltd.	1-4-7 Otemon, Chuo-ku, Fukuoka 810-0074
Shinsei Pharmaceutical Industry Co., Ltd.	1269 Shimizutani, Takatori-cho, Takaichi-gun, Nara 635-0103
Taiko Pharmaceutical Co., Ltd.	3-34-14 Uchihonmachi, Suita-city, Osaka 564-0032
Taikoseido Pharmaceutical Co., Ltd.	2-1-27 Azuma-dori, Chuo-ku, Kobe 651-0076
Taisho Pharmaceutical Co., Ltd.	3-24-1 Takada, Toshima-ku, Tokyo 170-8633
Takizawa Kampo Medicine Co., Ltd.	2-623-1 Horinouchi-cho, Ohmiya-ku, Saitama 330-0804
Tatebayashi Shokakudo Co., Ltd.	4-3-1 Higashiueno, Taito-ku, Tokyo 110-0015
Teikoku Kampo Seiyaku Co., Ltd.	636-1 Minato, Higashikagawa-city, Kagawa 769-2701
Tochimoto Tenkaido Co., Ltd.	3-21 Suehiro-cho, Kita-ku, Osaka 530-0053
Tohtohshu Seizo Co., Ltd.	6 Tenjin-cho, Shinjuku-ku, Tokyo 162-0826
Tokiwa Phytochemical Co., Ltd.	158 Kinoko, Sakura-shi, Chiba 285-0801
Toyo Yakuko Co., Ltd.	6-19-7 Hongo, Bunkyo-ku, Tokyo 113-0033
Tsumura & Co.	2-17-11 Akasaka, Minato-ku, Tokyo 107-8521
Uchida Wakanyaku Ltd.	5-11-10 Higashi-Nippori, Arakawa-ku, Tokyo 116-0014
Wakanyaku Medical Institute Ltd.	1-29-8 Shinjuku, Shinjuku-ku, Tokyo 160-0022
Yamamoto Kanpoh Seiyaku Co., Ltd.	156 Takihigashimachi, Komaki-city, Aichi 485-0035
Yatsume Seiyaku Co., Ltd.	2-14-14 Funabori, Edogawa-ku, Tokyo 134-0091
Yomeishu Seizo Co., Ltd.	16-25 Nanpeidai-cho, Shibuya-ku, Tokyo 150-8563
Zaiseido Pharmaceutical Co., Ltd.	8-31 Oda 2-chome, Wakayama-city Wakayama 640-8323
Zenyaku Kogyo Co., Ltd.	5-6-15 Otsuka, Bunkyo-ku, Tokyo 112-8650
Zeria Pharmaceutical Co., Ltd.	10-11 Nihonbashikobuna-cho, Chuo-ku, Tokyo 103-8351

* Alphabetical order of company name.

Related Organizations



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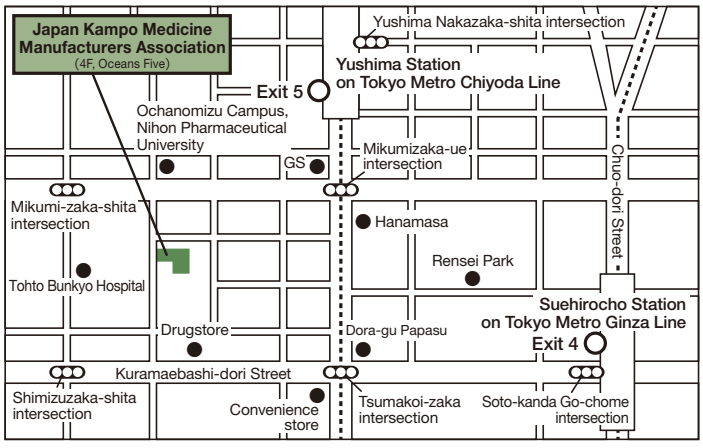
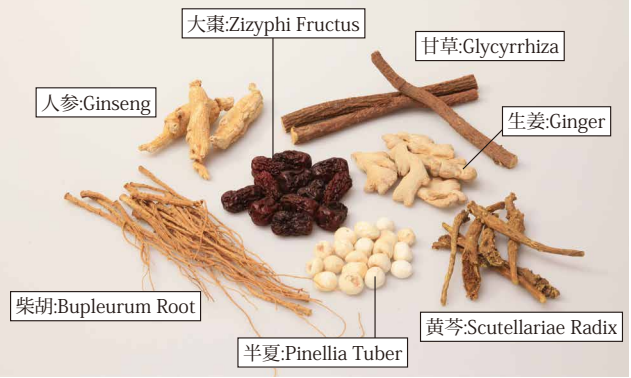


The nearest stations

Four-minute walk from Exit 5 of Yushima Station on Tokyo Metro Chiyoda Line

Five-minute walk from Exit 4 (Exit 2) of Suehirocho Station on Tokyo Metro Ginza Line

Shosaikoto (cover photo)



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