JPMA's Contribution to Global Health

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Japan Pharmaceutical Manufacturers Association

Background

Global health has greatly improved in recent years, as seen in significant increases in average life expectancy\(^1\). New medicines have played a major role in this success story. However, patients in many developing countries do not yet have sufficient access to the medical care, including medicines, that they need. Improving access to healthcare in those countries must therefore be the top priority on the international healthcare agenda. To respond to this challenge, it is vital that all stakeholders at national, regional and international levels play their parts and make serious efforts to solve the problems faced through cooperation and partnership.

As global health stakeholders, the Japan Pharmaceutical Manufacturers Association (JPMA) and its member companies recognize that it is our social mission to actively pursue the fulfillment of unmet medical needs. We acknowledge our responsibility to contribute to improved global health through provision of innovative new medicines to people around the world, taking “patient-centered healthcare” as our motto.

JPMA’s basic principle when engaging in international cooperative projects was established in 2009: “We sincerely face public health issues in an international framework, cooperate with various stakeholders such as governments and international organizations, and contribute to improvement of access to medicine of developing countries.”

As an important global health stakeholder, we will seek further cooperation with international organizations such as the United Nations and the World Health Organization (WHO), the governments of developing countries and of Japan, NGOs, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), and other relevant partners. JPMA and its members share a common understanding on the following global health issues:

1. **Innovation: Creation of medicines and vaccines**
2. **Three major infectious diseases and neglected tropical disease (NTDs)**
3. **Capacity building**
4. **Intellectual property system**
5. **Counter measures against counterfeit medicines**
6. **Non-Communicable Diseases (NCDs)**
7. **Trust and ethics**
8. **Others (examples of efforts)**

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\(^1\) Average life expectancy increased by 1.96 years between 1987 and 2000, with new medicines contributing up to 40% of this improvement in longevity. Lichtenberg, FR. “The impact of New Drug Launches on Longevity: Evidence for Longitudinal, Disease-Level Data from 52 Countries, 1982-2001”, International Journal of Healthcare Finance and Economics (2005) 5: 47-73
1. **Innovation: Creation of medicines and vaccines**

   The research and development (R&D) capacity of the Japanese pharmaceutical industry is of a global standard, which makes Japan one of few countries that can create new medicines. Through innovative research, development and manufacturing of high quality medicines and vaccines, the Japanese R&D-based pharmaceutical industry contributes to the prevention and treatment of diseases, to decreased early mortality, improvement of patients’ quality of life (QOL), avoidance of expensive hospitalization expenses, and the social rehabilitation of patients.

   In the present century we have seen remarkable progress in the field of life science, such as the development of individualized medicines, gene therapy and regenerative medicine. The JPMA and its members seek to continue to contribute to the improvement of people’s health across the world, bringing together these scientific advances and the latest technologies to create superior medicines.

   However, research and development activity is complex and creative in nature, with large amounts of money and time required for a new medicine to be brought to market, while success rates are very low. In addition to this general challenge, for the research and development of new medicines for diseases particularly prevalent in developing countries there is an additional difficulty that normal market principles often do not work. In order to solve these issues, flexible responses which create an environment that speeds up development of new medicines and facilitate R&D collaborations may be necessary.

   JPMA and its members will make active efforts to create the new medicines and vaccines needed, where necessary forming product development partnerships.

2. **Neglected tropical diseases (NTDs) and the three major infectious diseases**

   According to the WHO, three major infectious diseases, namely, HIV/AIDS, tuberculosis, malaria, plus NTDs (Neglected Tropical Diseases) are prevalent in 149 countries and territories around the world, with the number of patients suffering from these infections estimated to be over one billion. While NTDs flourish as a result of poverty, they are also the cause of poverty in many countries. Breaking this vicious circle is necessary for the economic growth of epidemic countries and for global development, but will require global solutions. In Japan too, movements have begun to solve these issues in developing countries through public-private partnership.

   JPMA and its members recognize that we are important stakeholders who can play an important role in improving access to medicines, including the development of new medicines to treat NTDs and other infectious diseases.

   **Examples of efforts by member companies**

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   2 Infectious diseases caused by parasites and bacteria which flourish mainly in tropical areas are called “Neglected Tropical Diseases, NTDs” because developed countries have not considered them major diseases so far. According to WHO, dengue fever, rabies, trachoma, Buruli ulcer, treponema infection, Hansen’s disease, Chagas’ disease, sleeping sickness, leishmaniasis, cysticerosis, Guinea worm infection, Echinococcosis, Foodborne trematode infections, Lymphatic filariasis, river blindness, schistosomiasis, and soil-transmitted helminthiasis are defined as NTDs.
3. **Capacity building**

In developing countries, access to medicines is obstructed by various factors, such as an inadequate public medical insurance system and medical infrastructure, shortfalls in the human resources needed for the manufacture and quality management of medicines, the spread of counterfeit medicines and poverty.

JPMA and its members believe that capacity building in developing countries – specifically know-how transfer and educational training – is an important part of improving access to medicines.

3-1) **Know-how transfer**

JPMA and its member companies are providing technical assistance in cooperation with stakeholders on the manufacture and quality management of pharmaceuticals in order to improve access to medicine in developing countries. As an example, JPMA designed and implemented a GMP (Good Manufacturing Practice) support project in Cambodia. We have also cooperated with Kanazawa University and national governments to conduct an anti-counterfeit medicine project in Cambodia and the Philippines. Through this project JPMA and its members helped achieve technical improvements in countermeasures against counterfeit medicines in these countries.

3-2) **Training**

In developing countries, patients are not always able to receive appropriate medical care due to a lack of medical resources and a shortage of skilled healthcare professionals. JPMA and its member companies, in cooperation with developing country governments, are working to improve the ability of healthcare professionals involved in disease prevention, diagnosis, and treatment to improve healthcare in these countries. For over 20 years, with the support of its member companies, JPMA has been providing drug quality management training in Japan and overseas for government officials from developing Asian countries in order to support human resource development and improve medicine quality in the ASEAN area. Furthermore, we offer specialist training for the prevention and treatment of AIDS, aimed at the prevention of infection and the improvement of patients’ Quality of Life (QOL), by working with the ASEAN Institute for Health Development (AIHD). JPMA and its members have also been supporting quality improvement seminars in Indonesia, in partnership with the Japanese government.

Examples of efforts by member companies

4. **Intellectual property system**

4-1) **Intellectual property and the development of new medicines**

All JPMA member companies work day-in and day-out to research and develop new medicines that will benefit patients around the world. In order for this R&D process to be sustainable, and to ensure access over time to innovative new treatments for patients, there is a need for a system in which patent rights, trademark rights, and other intellectual property such as clinical data are appropriately protected. This protection of intellectual property enables R&D to deliver the next new medicines and further enhances the social infrastructure and economy of each country.
4-2) IP and access to medicines in developing countries

JPMA and its member companies recognize the importance of delivering medicines for NTDs, as well as for infectious diseases such as HIV, tuberculosis, malaria, to patients in developing countries. While working within a framework that protects the results of research through intellectual property rights, we are keen to cooperate with other stakeholders in order to develop medicines for the diseases of the developing world and improve access to medicine, including where appropriate through public-private partnership. While intellectual property rights are essential, in order to improve access to medicines in developing countries and hence contribute to global health, JPMA and its members will implement the patent system in a flexible manner, considering non-application of these rights in certain countries and flexibility of the associated conditions in others.

Examples of efforts by member companies

4-3) Compulsory license

According to the agreement on trade-related aspects of intellectual property rights (TRIPS) issued by the World Trade Organization (WTO) in 1995, member states can invoke the right to grant a compulsory license for a technology in which a patent right is protected without obtaining prior authorization from the patent holder, under certain conditions. Based on the particular circumstance of a given country, a compulsory license as an emergency measure may be issued in order to protect peoples’ lives in not only developing but also developed countries. However, the issuing of compulsory licenses cannot in itself solve the issue of access to medicines. Where compulsory licenses are issued without rational justification or sufficient transparency, this will only serve to deter investment in the researching and developing of new medicines. JPMA and its members believe that constructive dialogue between government and the pharmaceutical industry is the most fruitful approach for improving sustainable access to medicines.

5. Countermeasures against counterfeit medicines

The threat of counterfeit medicines is increasing worldwide and the value of these products is estimated to have reached US$75 billion. In developing countries, it is reported that between 10% and 30% of distributed medicines are counterfeit, posing a serious threat to patient safety. Manufacturing and distributing counterfeit medicines while deliberately disguising them as authorized genuine medicines results not only in patients being denied the desired treatment effect, but also risks causing physical disability or death due to unexpected side effects. As a consequence, JPMA and its member companies will therefore make every effort to eradicate counterfeit medicines.

In July 2012, JPMA published a joint statement with the other major pharmaceutical industry associations, IFPMA, PhRMA and EFPIA, to support and encourage the efforts by national and

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3 At the WHO IMPACT conference, held in Hammamet, Tunisia in 2008, the term “counterfeit medicine” was defined as a medicine which is deliberately and fraudulently mislabelled with respect to identity and/or source.
international government organizations to reduce the illegal sale of medicines by illegitimate online
drug sellers that endanger public health.

The Japanese government has also announced work on countermeasures against counterfeit
medicines through public-private cooperation, and it intends to establish a website to educate the
general public in Japan. JPMA welcomes and supports these efforts.

Although the aim of anti-counterfeiting efforts is to protect patient health, in practice cracking
down on the infringement of trademark rights, can be an effective tool as a countermeasure against
counterfeit medicines.

JPMA and its members recognize that substandard medicines are an important issue. However,
substandard medicines, which are a manufacturing quality problem, are different from counterfeit
medicines. Nevertheless, a substandard medicine could pose a serious health risk to patients, and
JPMA strongly supports the highest standards for all patients across the world. We will therefore
make efforts to solve the problem of substandard medicines using various methods, including
where appropriate public-private cooperation, working to raise technical ability in developing
countries to international standards.

Some JPMA member companies have established internal global functions to deal with issues
related to securing the safety of medicines, including countermeasures against counterfeit
medicines, and are contributing funding to activities to eradicate the criminal trade in counterfeit
medicines. The JPMA itself is also currently conducting a survey of its membership regarding
counterfeit medicines, which will help in preparation of further measures to support developed and
developing countries suffering from counterfeit medicines.

6. Non-Communicable Diseases, NCDs

Non-communicable diseases⁴ are the number one cause of death not only in developed countries
but also in many developing countries. Among the global death toll of 57 million in 2008, 36
million people (63%) died due to NCDs⁵.

Based on this situation, the United Nations and WHO have put “prevention and management of
NCDs” towards the top of their agendas, setting a goal of “25 by 25” (reducing the rate of
premature mortality due to NCDs by 25% by 2025), and are currently developing an execution plan
for 2013-2020. WHO believes that the prevention and management of NCDs should not be
confined only to the scope of healthcare, but should also be addressed as a socio-economic issue
because of its impact on healthcare finance and the economies of each country. WHO is therefore
considering countermeasures focused on middle and low income countries, and has identified
smoking, insufficient exercise, inappropriate diet, and excessive alcohol consumption as the main
NCD risk factors.

IFPMA announced its “Framework for Action for the Prevention and Control of NCDs” in June

⁴ Among non-communicable diseases, WHO specifically treats cardiovascular diseases, cancer, diabetes and
chronic obstructive pulmonary diseases as NCDs.
⁵ World Health Organization, "Global Status Report on non-communicable diseases 2010" Introduction p. vii
2011, and has made NCDs a top-level priority. As a first step of action, IFPMA has conducted a survey of access to treatment medicines for NCDs in developing countries. JPMA supports the IFPMA Framework and will seek possible cooperation with various stakeholders in order to help improve the prevention and control of NCDs.

JPMA member companies continue to make great efforts to research and develop innovative new medicines in the NCDs field, and continue to seek ways to improve access to these new medicines not only in developed countries but also in developing countries.

Examples of efforts by member companies

7. Trust and ethics

The true nature of a medicine cannot be determined solely from its appearance. In order to understand both the effects and possible side effects of a medicine, the correct information is required: without this the product cannot function effectively as a medicine. Provision of information which lacks appropriate balance of effects and side effects, or inappropriate sales activities, not only promote the incorrect use of medicines and interfere with optimal treatments for patients, but may also cause a harmful effect on patient health. Therefore, pharmaceutical companies bear a serious responsibility to provide accurate, fair, and scientifically grounded information for their products, so that the appropriate use of medicines can be facilitated. This responsibility is universal, and applies in both developed and developing countries.

In recent years, the demand for pharmaceutical companies regarding ethics and transparency from stakeholders has increased. R&D-based pharmaceutical companies need to show that they operate according to high ethical standards at all times, thereby earning a higher degree of trust from society for them to accomplish their mission.

When interacting with medical professionals, JPMA member companies adhere to the JPMA “Promotion Code for Prescription Drugs”, which is based on the “IFPMA Code of Practice”. The JPMA Code covers promotion activities for medicines, with the goal of achieving optimal treatments for patients.

In addition, JPMA member companies develop their own guidelines in line with the following JPMA publications: “Guidelines for transparency of the relationship between cooperate activities and medical institutions”, and “Guidelines for transparency of the relationship between cooperate activities and patient groups”. Over 2013 and 2014, JPMA member companies will begin to implement information disclosure practices which comply with these guidelines.

JPMA, as a member of the IFPMA Code Compliance Network, actively participates in activities such as promoting further diffusion of the IFPMA Code and discussions about possible revisions. JPMA also participated in development of the “Mexico City Principles”, a voluntary business code of ethics in the pharmaceutical industry approved at the APEC ministerial meeting in 2011. JPMA works to promote ethical business practices for the promotion and sale of medicines based on these principles, into developed countries and developing countries, and into R&D-based pharmaceutical companies and other pharmaceutical companies, regardless of company size.
JPMA contributes to patient health through its activities to establish and disseminate high global ethical standards.

8. Others
8-1) Examples of efforts by domestic member companies
8-1-1) Three major infectious diseases and NTDs6

- Free provision of lymphatic filariasis treatment medicines
  Eisai Co., Ltd. has committed to provide 2.2 billion tablets of diethylcarbamazine (DEC) for free to WHO between 2013 and 2020, as a part of the lymphatic filariasis elimination program.

- Development and sales of malaria drug
  Ranbaxy Laboratories Limited, a subsidiary of Daiichi Sankyo Company Limited, succeeded in developing a malaria treatment which became the first new drug by an Indian company, and currently sells the drug domestically in India. Ranbaxy plans to actively distribute this drug to areas that have many cases of malaria infection, such as South-East Asia and Africa.

- Development of HIV infection drug
  Shionogi-ViiV Healthcare LLC, which Shionogi & Co., Ltd. and ViiV Healthcare established together, is working to develop a next generation integrase inhibitor, dolutegravir. Currently, four phase III clinical trials are being conducted, mainly in Europe and the US, and a New Drug Application will be made by the end of 2012.

- Development of tuberculosis drugs
  For the past 30 years, Otsuka Pharmaceutical Co., Ltd. has been engaged in research and development to create medicines aimed at eradicating tuberculosis. Otsuka’s new tuberculosis drug, delamanid, which produced excellent results in a phase II clinical trial for multidrug-resistant tuberculosis, is currently under application for marketing approval in Europe. Also, a phase III trial is ongoing to confirm the results of the late-stage phase II trial.

- Development of Chagas disease drug
  Eisai Co., Ltd. and DNDi (Drugs for Neglected Diseases initiative), an international independent non-profit organization, are implementing a clinical trial for a new antymycotic drug against the pathogen that causes Chagas disease. Eisai provides scientific expertise and quantities of the drug required for clinical trials, while DNDi conducts clinical development in areas where Chagas disease is prevalent.

- Development of pediatric preparation of schistosomiasis infection drug

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6 Examples were quoted from ones in late stage of development, based on a press release and published contents on a home page.
Astellas Pharma Inc. established an international public-private partnership with TI Pharma, Merck KGaA, and the Swiss Tropical and Public Health Institute to develop a preparation for preschool children of praziquantel, which is effective for schistosomiasis.

- **Research and development of pediatric medicines for HIV infection**
  Daiichi Sankyo Company Limited is promoting an R&D project for HIV infection drugs (including new dosage forms) intended for children in sub-Saharan Africa, through its subsidiary Ranbaxy.

- **Development of tuberculosis and dengue fever drugs**
  Daiichi Sankyo Company Limited is cooperating with the Department of Science and Technology of India, Council of Scientific and Industrial Research to conduct an R&D program (chemical compound screening) for tuberculosis and dengue fever drugs at the Life Science Research Center in India.

- **Development of malaria drugs**
  Eisai Co., Ltd. is conducting drug discovery research into a toll-like receptor (TLR) 9 antagonist as a possible treatment against malaria. In addition, Eisai is conducting research to identify GWT1, which is one of the biosynthetic enzymes of malarial parasites, and to search for its inhibitors.

- **Development of drugs for Chagas disease, leishmaniasis and African sleeping sickness**
  Astellas Pharma Inc. and DNDi are conducting collaborative research to develop medicines for three NTDs (leishmaniasis, Chagas disease, and African sleeping sickness). Astellas selects its own chemical compounds and provides them to DNDi, and DNDi implements re-profiling of the compounds to evaluate the possibility as an anti-parasite drug candidate for the three diseases of interest.

- **Development of vaccines for Chagas’ disease and leishmaniasis**
  Eisai Co., Ltd. supports development of vaccines targeting Chagas disease and leishmaniasis, by providing vaccine adjuvant which Eisai created to the Sabin Vaccine Institute, a non-profit organization specialized in vaccine treatments and the study of NTDs.

- **Participation in the London Declaration on Neglected Tropical Diseases**
  Eisai Co., Ltd was one of 13 pharmaceutical companies that participated in the London Declaration on 30 January, 2012, which pledges commitment to control ten NTDs by 2020. Also taking part were the Bill and Melinda Gates Foundation, WHO, the World Bank, the US and UK governments, and governments of countries in which NTDs are prevalent.

8-1-2) **Capacity building**

- **Financial assistance to cultivate and reinforce healthcare human resource**
  Takeda Pharmaceutical Company Limited is implementing a donation program, the “Takeda Initiative”, to cultivate and reinforce healthcare human resources in Africa through the Global Fund to Fight AIDS, Tuberculosis and Malaria. A total of 1 billion yen (US$12 million) is
planned to be donated over 10 years from 2010 to 2019.

- **Acceptance of fellows and provision of trainings in developing countries**
  Astellas Pharma Inc. and Eisai Co., Ltd. have each accepted Fellows (trainees) from developing countries at their overseas offices through the WHO-TDR (WHO’s Special Programme for Research and Training in Tropical Diseases) Clinical Research Fellowships. Clinical researchers were provided with specialist training and hands-on experience, in order to build capacity in clinical development in the developing world. Eisai accepted one Fellow in 2010-11, while Astellas and Eisai each accepted Fellows in 2011-12.

- **Technical support for mass production of influenza vaccine**
  The Chemo-Sero-Therapeutic Research Institute (KAKETSUKEN) is providing the Thailand National Pharmaceutical Organization with technical support for mass production of influenza vaccine.

- **Mobile medical services to improve access to healthcare**
  Daiichi Sankyo Company Limited is implementing a mobile medical service in India, Tanzania and Cameroon. Medical services, including basic medical care, vaccination, medical checkups for pregnant women and infants, and health education are provided using mobile health clinics, supported by Daiichi Sankyo’s donation of 200 million yen (US$2.5 million) over five years from 2011.

8-1-3) Intellectual property system

- **Participation in WIPO research consortium (WIPO Re:Search)**
  Eisai Co., Ltd. has joined the “WIPO Re:Search” consortium, an international initiative to develop drugs for treating NTDs, TB and malaria, hosted by the World Intellectual Property Organization (WIPO). Each member organization provides for free intellectual property and R&D know-how for drugs and candidate compounds that may help treat these diseases, sharing this knowledge with researchers and research institutes interested in developing new medicines.

8-1-4) Non-Communicable Diseases (NCDs)

- **Anti-dementia and depression program through public-private cooperation**
  Eisai Co., Ltd. is developing a public-private collaborative business model to improve access to medicines in India, together with Apollo Hospitals and HelpAge India. The three organizations plan to implement programs to improve education, medical care, diagnosis, treatments and medical compliance for patients with Alzheimer’s disease and depression.

8-2) International cooperative projects by JPMA

JPMA published a brochure detailing the international cooperative projects conducted by JPMA itself and by its member companies (April, 2012).
8-3) Developing World Health Partnerships Directory (IFPMA)

The above list is not exhaustive - many JPMA member companies other than those described above are engaged in various activities intended to improve global health. In particular, although the examples given above are drawn from Japan-headquartered companies, the parent companies of many of the overseas-headquartered JPMA member companies are engaged in a very large number of programs aimed at achieving better health outcomes for people in developing countries. These activities are included in those published on the IFPMA web site in the Developing World Health Partnership Directory, which lists all the partnerships for developing countries engaged in by IFPMA member associations and member companies.

http://partnerships.ifpma.org/