Chapter 3

Legislative and Enforcement Processes and Types of Pharmaceutical Affairs-related Information

OBJECTIVES

- To understand legislative and enforcement processes (from draft preparation to promulgation of laws) in Japan.
- To understand the legal system and the composition of the Pharmaceutical Affairs Law.
- To obtain information on types and sources of pharmaceutical affairs-related information.

RELATED LAWS AND REGULATIONS

- Pharmaceutical Affairs Law (Law No. 145 of Showa 35 (1960))
- Pharmaceutical Affairs Law, Enforcement Ordinance (Government Ordinance No. 11 of Showa 36 (1961))
- Pharmaceutical Affairs Law, Enforcement Regulations (Ministry of Health and Welfare Ordinance No. 1 of Showa 36 (1961))
- Pharmaceutical Affairs Law-related Ministerial Ordinances and Announcements
- Articles 56, 65, and 66, etc. of the Diet Act (Law No. 79 of Showa 22 (1947))

Introduction

Laws, ethics and morals are some examples of regulations on our actions, and all of these are considered norms in society. Norms are “standards that one must comply with when acting or making decisions” (cited from the dictionary, Daijirin). Laws can be considered enforced norms for maintaining social order. They are established in the Diet, which represents the people of Japan.

This chapter, from among these norms, discusses laws. First, it will explain general legislative and enforcement processes and then the constitution of, and legal systems of, the Pharmaceutical Affairs Law, which regulates the industries of pharmaceutical products and medical devices, etc., and, finally, types of information regarding pharmaceutical affairs regulations and methods for obtaining such information will be described.

Legislative and Enforcement Processes

There are basically two ways to propose and submit a law to the Diet. One method involves the Cabinet submitting a bill and the other involves members of the Diet submitting a bill.

Cabinet bills are submitted by the Prime Minister as a representative of the Cabinet. When the members of the Diet submit a bill, it cannot be submitted by only one member. The Diet Act stipulates that more than 20 supporters in the House of Representatives and more than 10 supporters in the House of Councilors are required. Furthermore, for the submission of bills involving budgets, the Diet Act stipulates that more than 50 supporters in the House of Representatives and more than 20 supporters in the House of Councilors are required.

In addition, Legislation Bureaus (known as Legislative Bureaus of the Houses of the Diet) are set up in both the House of Representatives and the House of Councilors. In contrast with the Cabinet Legislation Bureau, which mainly reviews texts, these bureaus participate from the stage of formulating the concepts of a bill and support
members of the Cabinet in preparing a bill by engaging in fact-finding, etc.

An outline of the processes of a Cabinet bill, which is a commonly used method for submitting a bill, from proposal of the bill to its establishment and promulgation is shown in Figure 3-1 (as of June 2009).

**Preparation of a Draft Bill**

A draft bill presented by the Cabinet is prepared by the ministries with jurisdiction over the particular area. In order to realize the policy goals of the presiding administration, each ministry creates first drafts of bills when it is decided to establish new laws or to revise or repeal existing laws.

Based upon the first draft, consultations take place with other relevant ministries and the governing party. Moreover, when there is a need for deliberations for a Council or a hearing of opinions at a public hearing, such procedures will be arranged.

When the bill is ready to be submitted, the principal ministry writes the bill into law and a draft of the bill is prepared.
Examination by the Cabinet Legislation Bureau

Legislative bills submitted by the Cabinet are examined by the Cabinet Legislation Bureau before being brought before Cabinet meetings.

In principle, examinations by the Cabinet Legislation Bureau should begin only after a request addressed to the Prime Minister for a Cabinet meeting related to the bill is sent by the ministry in charge. In recent administrative practice, however, a method has developed whereby the bureau conducts a preliminary examination of the drafts of legislative bills for which the opinions of the principle ministries have been finalized. Therefore, Cabinet meetings are conducted based upon legislative bills that have undergone preliminary examination at the Cabinet Legislation Bureau.

During the examination by the bureau, each bill is examined from all angles, including legal and technical aspects, for the following points:

- the relationship between the proposed bill on one hand and the constitution and other existing laws on the other, as well as the legal validity of the content of the bill
- whether or not the intent of the proposed bill is accurately expressed in the text
- whether or not the structure of the bill, such as expressions and arrangement of provisions, is appropriate
- whether the usage of words and nomenclature is correct

Once the preliminary examination is completed, the state minister in charge of the legislative bill follows the procedure for sending a request for a Cabinet meeting regarding the submission of the bill to the Diet to the Prime Minister. The Cabinet Secretariat, which receives the request, sends it to the Cabinet Legislation Bureau. The Cabinet Legislation Bureau conducts a final examination while considering the results of the preliminary examination, makes any necessary revision, and returns the bill to the Cabinet Secretariat.

Cabinet Decision to Submit the Bill to the Diet

A synopsis of the legislative bill for which a Cabinet meeting has been requested is distributed to the attendees of the Cabinet meeting from the chief of the Cabinet Legislation Bureau, and if the bill is approved in a Cabinet meeting without objections, the Prime Minister submits the bill to the Diet (either to the House of Representatives or to the House of Councilors). Administrative duties related to the submission to the Diet of legislative bills submitted by the Cabinet are conducted by the Cabinet Secretariat.

Examination by the Diet

When a legislative bill is submitted by the Cabinet to either the House of Representatives or the House of Councilors, in principle, the leader of the house that receives the submission refers the bill to the appropriate committee (Article 56 of the Diet Act).

The committee then conducts an examination, starting with an explanation by the state minister regarding the reasons for proposing the bill. The examination largely follows a question-and-answer format regarding the legislative bill. When the committee completes its questioning and deliberations, the chairperson adjudicates any issues and a vote is taken. When the committee finishes the examination of the legislative bill, deliberations continue at a plenary session.

When the legislative bill submitted by the Cabinet passes both the committee and plenary session of the house (either the House of Representatives or House of Councilors) to which it was first submitted, the legislative bill is sent to the other house. The procedures involving deliberation and decisions both by a committee and a plenary session are also conducted at the house that receives the bill.

Enactment of a New Law

Unless otherwise specified by the constitution, a legislative bill becomes a law when it passes both the House of Representatives and the House of Councilors. When the new law is enacted, the leader of the latter house submits it to the Emperor via the Cabinet (Article 65 of the Diet Act).

Promulgation of the New Law

After the law is enacted, it must be promulgated within 30 days from the date on which the leader of the latter house submits it to the Emperor via the Cabinet (Article 66 of the Diet Act).

Once a Cabinet decision is made, the law is promulgated by being published in Kanpo, an official gazette. The law is numbered with a Law Number and is jointly signed by the state minister in charge and the Prime Minister.

Promulgation ensures that a newly enacted law becomes widely known by the public, enabling the people of Japan to know about the law. To make the law come into effect and enter into force, it must be promulgated.

In addition, “enforcement” is when the law generally and actually comes into effect and enters into force, and the period when the promulgated law becomes effective is stipulated in the attached clauses.

Composition of the Legal System and of the Pharmaceutical Affairs Law

Legal System

There is a wide variety of laws, including the criminal code and civil code. Laws regarding pharmaceutical affairs include the Pharmaceutical Affairs Law and the Pharmacists Law. All laws are enacted after a Cabinet meeting and guaranteed under the Constitution of Japan. Therefore, laws cannot go beyond the framework of the constitution.
Similarly, the legal system has a graduated structure in which government ordinances are ranked under laws, and ministerial ordinances are ranked under laws and government ordinances. Figure 3-2 presents a schematic of this system.

The term “laws and ordinances” is generally used when referring to both laws and ordinances. “Laws” are enacted via Cabinet meetings, and “ordinances” are enacted by national administrative institutions based upon laws without holding a Cabinet meeting (“Dictionary of Legal Terms,” Yuhikaku). Government ordinances, ministerial ordinances and announcements, fall under the category of ordinances.

Laws and ordinances are promulgated and become legally effective by being published in Kanpo. Although there are no statutory laws regarding promulgation, it is based upon practices from the Meiji period and cases from the Supreme Court (from the Government Data Research Center of Japan website).

Next, the definitions of and relationships and differences between laws, government ordinances, ministerial ordinances, announcements, notifications, administrative notices, etc. that are issued will be explained.

What Is a “Law?”
A law is enacted via a Cabinet meeting and promulgated by being published in Kanpo. Although there are no statutory laws regarding promulgation, it is based upon practices from the Meiji period and cases from the Supreme Court (from the Government Data Research Center of Japan website).

What Is a “Government Ordinance?”
These have more specific contents than laws and are ordinances decided by the Cabinet (in a Cabinet meeting).

Ordinances enacted by the Cabinet will be described in the section for “Government Ordinances” in Kanpo. There are two types of orders for government ordinances: orders of enforcement (enforcement ordinances) enacted in order to implement the provisions of the constitution and laws, and delegated orders enacted based on the delegation of laws. Names such as “XX Law, Enforcement Ordinance” and “Government ordinance regarding XX” are used for orders of enforcement and delegated orders, respectively.

Government ordinances regarding pharmaceutical affairs include the Pharmaceutical Affairs Law, Enforcement Order (Government Ordinance No. 11, Showa 36 (1961)) and the Cabinet Order for Fees Related to the Pharmaceutical Affairs Law (Government Ordinance No. 91, Heisei 17 (2005)).

The relationship between laws and government ordinances is, for example, as follows.

- Article 2 (Definitions), Paragraph 4 of the Pharmaceutical Affairs Law: “The term ‘medical device’ in this law refers to medical equipment, etc. [...] that are designated by a Cabinet order.”

- Article 1 of the Pharmaceutical Affairs Law, Enforcement Ordinance (Scope of medical devices): “Medical devices specified in Article 2, Paragraph 4 of the Pharmaceutical Affairs Law (hereinafter referred to as ‘Law’) are as defined in Appendix 1.”

What Is a “Ministerial Ordinance?”
This is an ordinance that each ministry may issue with respect to administrative affairs under its charge in order to enforce a law or government ordinance, or an ordinance issued based upon a special delegation of a law or government ordinance (Article 12, Paragraph 1 of the National Government Organization Law). There are two types of ministerial ordinances, and names such as XX Law, Enforcement Regulations and Ministerial ordinance regarding XX are used for orders of enforcement and delegated orders, respectively.

Examples of ministerial ordinances related to the Pharmaceutical Affairs Law (popular name then formal name) are listed below along with examples of the relationship between these ministerial ordinances and the Pharmaceutical Affairs Law.

Ministerial Ordinances related to the Pharmaceutical Affairs Law

- Enforcement Regulations: Pharmaceutical Affairs Law, Enforcement Regulations (Ministry of Health and Welfare Ordinance No. 1, Showa 36 (1961))
- Ministerial Ordinance on GQP: Ministerial
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Ordinance on Standards for Quality Control for Drug Products, Quasi-drugs, Cosmetics, and Medical Devices (Ministry of Health, Labour and Welfare Ordinance No. 136, Heisei 16 (2004)).

• Ministerial Ordinance on GVP: Ministerial Ordinance on Standards for Post-Marketing Safety Management System for Drug Products, Quasi-drugs, Cosmetics, and Medical Devices (Ministry of Health, Labour and Welfare Ordinance No. 135, Heisei 16 (2004)).

• Ministerial Ordinance on QMS for Medical Devices and In Vitro Diagnostics: Ministerial Ordinance on Standards for Manufacturing Control and Quality Control for medical devices and in vitro diagnostics (Ministry of Health, Labour and Welfare Ordinance No. 169, Heisei 16 (2004))

• Ministerial Ordinance on GMP for Drug Products: Ministerial Ordinance on Standards for Manufacturing Control and Quality Control for Drug Products and Quasi-drugs (Ministry of Health, Labour and Welfare Ordinance No. 179, Heisei 16 (2004))

• Ministerial Ordinance on GCP for Drug Products: Ministerial Ordinance on Standards for Good Clinical Practice for Drug Products (Ministry of Health and Welfare Ordinance No. 28, Heisei 9 (1997))

• Ministerial Ordinance on GCP for Medical Devices: Ministerial Ordinance on Standards for Good Clinical Practice for Medical Devices (Ministry of Health, Labour and Welfare Ordinance No. 36, Heisei 17 (2005))

• Ministerial Ordinance on GLP for Drug Products: Ministerial Ordinance on Standards for Good Laboratory Practice for Safety of Drug Products (Ministry of Health and Welfare Ordinance No. 21, Heisei 9 (1997))

• Ministerial Ordinance on GLP for Medical Devices: Ministerial Ordinance on Standards for Good Laboratory Practice for Safety of Medical Devices (Ministry of Health, Labour and Welfare Ordinance No. 37, Heisei 17 (2005))

• Ministerial Ordinance on GPSP for Drug Products: Ministerial Ordinance on Standards for Good Postmarketing Study Practice for Drug Products (Ministry of Health and Welfare Ordinance No. 171, Heisei 16 (2004))

• Ministerial Ordinance on GPSP for Drug Products: Ministerial Ordinance on Standards for Good Postmarketing Study Practice and Clinical Practice for Drug Products (Ministry of Health and Welfare Ordinance No. 38, Heisei 17 (2005))

Examples of the Relationship Between the Pharmaceutical Affairs Law and the Ministerial Ordinances

- Article 14, Paragraph 3 of the Law (Approval for manufacturing and marketing of drug products, etc.): “Parties wishing to obtain approval as described in Paragraph 1... shall attach documents on the results of clinical trials and other pertinent information to their relevant applications as specified by the ordinances of the Ministry of Health, Labour and Welfare. In this case [...]”

• Article 40 of the Enforcement Regulations: “... attachments shall be made to the application documents described in Article 38 or 46 based on the provisions of Article 14, Paragraph 3 of the Law.”

- Article 5, Section 1 of the Law (Licensing standards): “When any of the following items applies, the licenses described in paragraph 1 of the previous Article may be withheld. [...] When the buildings and facilities for the pharmacy do not conform to the standards stipulated in the ordinances of the Ministry of Health, Labour and Welfare.”

• Section 1 of Article 12-2 of the Law (Conditions for licenses): “When quality control methods for drug products, quasi-drugs, cosmetics, and medical devices related to the application are not compliant with the standards stipulated in the ordinances of the Ministry of Health, Labour and Welfare.”

• Article 1 of the Ministerial Ordinance on GQP (Purpose): “This ordinance specifies the standards specified in the ordinances of the Ministry of Health, Labour and Welfare prescribed in Section 1 of Article 12-2 of the Pharmaceutical Affairs Law.”

• Section 2 of Article 12 of the Law (Conditions for licenses): When methods for post-manufacturing and marketing safety management (collection and review of information necessary for matters regarding quality, effectiveness and safety as well as other appropriate usage, and necessary measures based upon the results) of drug products, quasi-drugs, cosmetics and medical devices related to the
application are not in compliance with the standards specified in the ordinances of the Ministry of Health, Labour and Welfare.

- Article 1 of the Ministerial Ordinance on GVP (Purpose): “This ordinance specifies the standards specified in the ordinances of the Ministry of Health, Labour and Welfare regarding post-manufacturing and marketing safety management prescribed in Section 2 of Article 12-2 of the Pharmaceutical Affairs Law.”

- Section 4 of Article 14, Paragraph 2 of the Law (Approval for Manufacturing and Marketing Drug Products): “When drug products, quasi-drugs, cosmetics, and medical devices related to the application are [...], methods for manufacturing control and quality control at the manufacturing sites are not confirmed as being in compliance with standards specified in the ordinances of the Ministry of Health, Labour and Welfare.”

- Article 1 of the Ministerial Ordinance on GMS (Purpose): “This ordinance specifies the standards specified in the ordinances of the Ministry of Health, Labour and Welfare prescribed in Section 4 of Article 14-2 of the Pharmaceutical Affairs Law.”

- Article 14, Paragraph 3 of the Law: “For the approval described in Section 1, [... ] must be attached with the application. In this case, when the drug products or medical devices related to the application are those specified the ordinances of the Ministry of Health, Labour and Welfare, such materials shall be collected and created based on the standards specified by the Minister of Health, Labour and Welfare.”

- Article 1 of the Ministerial Ordinance on GCP for Medical Devices (Purpose): “This ordinance specifies matters related to good clinical practice for medical devices in the standards specified by the Minister of Health, Labour and Welfare prescribed in Article 14, Paragraph 3 of the Pharmaceutical Affairs Law.”

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**What Is a “Ministerial Ordinance?”**

Public institutions officially announce the decisions they make on issues within their jurisdiction and other certain...
## Legislative and Enforcement Processes and Types of Pharmaceutical Affairs-related Information

### Table 3-1. List of Sources of Information Related to Administrations and Other Pharmaceutical Affairs (Cont’d.)

<table>
<thead>
<tr>
<th>Institution Name</th>
<th>Web Addresses</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Prefectural governments</strong></td>
<td></td>
</tr>
</tbody>
</table>
| | o Notifications related to pharmaceutical affairs, etc.  
| | (Health and safety, drug product safety, notifications related to pharmaceutical affairs, etc.) [http://www.fukushihoken.metro.tokyo.jp/kenkou/iyaku/yakuikankeituuchitou/index.htm](http://www.fukushihoken.metro.tokyo.jp/kenkou/iyaku/yakuikankeituuchitou/index.htm) |
| | • Mie [http://www.pref.mie.jp/](http://www.pref.mie.jp/)  
| • Kyoto | • Kyoto [http://www.pref.kyoto.jp/yakujikaisei/](http://www.pref.kyoto.jp/yakujikaisei/)  
| • Toyama | • Toyama Pharmaceutical/Health Information Library [http://tominet.jp/](http://tominet.jp/)  
| • Others | • Japan Association for the Advancement of Medical Equipment (refer to the addresses of institutions related to public offices) [http://www.jaame.or.jp/](http://www.jaame.or.jp/)  
| | • History of medical devices [http://www.jaame.or.jp/ken_zai/index.html](http://www.jaame.or.jp/ken_zai/index.html)  
| | • Notifications of new administrations [http://www.jaame.or.jp/sinki/sinki.html](http://www.jaame.or.jp/sinki/sinki.html)  
| | • Contact lists/related books [http://www.jaame.or.jp/yusyo/yusyo.html](http://www.jaame.or.jp/yusyo/yusyo.html)  
| | o Addresses of institutions related to public offices [http://www.jaame.or.jp/yusyo/kouju.html](http://www.jaame.or.jp/yusyo/kouju.html)  
| | o Contact list of institutions related to public offices [http://www.jaame.or.jp/yusyo/kanju.html](http://www.jaame.or.jp/yusyo/kanju.html)  
| | o Information on books related to medical devices [http://www.jaame.or.jp/yusyo/BOOK.html](http://www.jaame.or.jp/yusyo/BOOK.html) |
| **Japan Association for the Advancement of Medical Equipment (JAAME)** | [http://www.jaame.or.jp/](http://www.jaame.or.jp/)  
| | • History of medical devices [http://www.jaame.or.jp/ken_zai/index.html](http://www.jaame.or.jp/ken_zai/index.html)  
| | • Notifications of new administrations [http://www.jaame.or.jp/sinki/sinki.html](http://www.jaame.or.jp/sinki/sinki.html)  
| | • Contact lists/related books [http://www.jaame.or.jp/yusyo/yusyo.html](http://www.jaame.or.jp/yusyo/yusyo.html)  
| | o Addresses of institutions related to public offices [http://www.jaame.or.jp/yusyo/kouju.html](http://www.jaame.or.jp/yusyo/kouju.html)  
| | o Contact list of institutions related to public offices [http://www.jaame.or.jp/yusyo/kanju.html](http://www.jaame.or.jp/yusyo/kanju.html)  
| | o Information on books related to medical devices [http://www.jaame.or.jp/yusyo/BOOK.html](http://www.jaame.or.jp/yusyo/BOOK.html) |
| **Government Data Research Center of Japan** | [http://www.gioss.or.jp](http://www.gioss.or.jp)  
| | • Items related to public bulletins [http://www.gioss.or.jp/clip/kanpou2.htm](http://www.gioss.or.jp/clip/kanpou2.htm) |
| **Industry groups** | |
| • Japan Federation of Medical Devices Association (JFMDA) | [http://www.jfmda.gr.jp/index.htm](http://www.jfmda.gr.jp/index.htm)  
| • Other independent organizations | [http://www.advamed.org/](http://www.advamed.org/)  
| • Advanced Medical Technology Association (AdvaMed) | [http://www.amdd.jp/](http://www.amdd.jp/)  
| • American Medical Devices and Diagnostics Manufacturer’s Association (AMDD) | [http://www.ebc-jp.com/index-J.htm](http://www.ebc-jp.com/index-J.htm)  
| • European Business Council in Japan (EBC) | |
### Table 3-2. List of Organizations Related to Medical Devices

List of JFMDA member organizations
(As of August 2009, from the Japan Federation of Medical Devices Association website)

<table>
<thead>
<tr>
<th>Name of Organization (abbreviation)</th>
<th>Major Product Lines/Businesses</th>
<th>Address/Phone Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Japan Industrial Association of Radiological Systems (JIRA)</td>
<td>Diagnostic X-ray devices, X-ray CT devices, MR devices, X-ray film, etc.</td>
<td>Sumitomo Fudosan Hongo Building 9F, 3-22-5 Hongo, Bunkyo-ku, 113-0033&lt;br&gt;Phone: +81 3 3816 3450</td>
</tr>
<tr>
<td>Japan Electronics and Information Technology Industries Association Medical electronic system business committee (JEITA)</td>
<td>Devices for recording measurements of biological phenomena, devices for image inspections, medical systems, ultrasonic diagnostic imaging devices, etc.</td>
<td>Chiyoda First Building South Wing, 3-2-1 Nishi Kanda, Chiyoda-ku, 101-0065&lt;br&gt;Phone: +81 3 5275 7261</td>
</tr>
<tr>
<td>Japan Medical Devices Manufacturers Association (JMED)</td>
<td>Anesthesia machines, artificial ventilators, pacemakers, operating equipment and supplies such as surgical scalpels, clinical equipment and supplies such as surgical beds, etc.</td>
<td>Ikakikai Kan 5F, 3-39-15 Hongo, Bunkyo-ku, 113-0033&lt;br&gt;Phone: +81 3 3816 5575</td>
</tr>
<tr>
<td>Japan Medical Devices Manufacturers Association (JMED)</td>
<td>Disposable products (syringes/catheters, etc.), artificial joints, artificial bones/materials, devices for artificial kidneys, dialyzers, artificial hearts, artificial lungs, artificial pancreases, artificial blood vessels, artificial cardiac valves, etc.</td>
<td>Kamiura Kojimachi Building 3F, 3-10-3 Kojimachi, Chiyoda-ku, 102-0083&lt;br&gt;Phone: +81 3 5212 3721</td>
</tr>
<tr>
<td>Japan Association of Health Industry Distributors (JAHID)</td>
<td>Marketing of medical devices/medical supplies</td>
<td>KOGA Building 4F, 3-39-17 Hongo, Bunkyo-ku, 113-0033&lt;br&gt;Phone: +81 3 5689 7530</td>
</tr>
<tr>
<td>Japan Home-health Apparatus Industrial Association (Home health)</td>
<td>Domestic low-frequency therapy equipment, domestic electric therapy equipment, domestic infusion equipment, domestic massage equipment, etc.</td>
<td>Nanzando Building 5F, 4-1-11 Yushima, Bunkyo-ku, 113-0034&lt;br&gt;Phone: +81 3 5805 6131</td>
</tr>
<tr>
<td>Japan Medical-Optical Equipment Industrial Association (JMOEIA)</td>
<td>Medical endoscopes, ophthalmologic equipment, lenses for eyewear, eyewear equipment, etc.</td>
<td>Risshu Building 3F, 2-2-3 Nihonbashi, Chuo-ku, 103-0027&lt;br&gt;Phone: +81 3 6225 5474</td>
</tr>
<tr>
<td>Japan Dental Trade Association (JDTA)</td>
<td>Dental equipment, dental materials, dental drugs (businesses of manufacturing, importing, distribution)</td>
<td>Nihon Shika Kikai Kaikan, 2-16-14 Kojima, Taito-ku, 111-0056&lt;br&gt;Phone: +81 3 3851 3450</td>
</tr>
<tr>
<td>Japan Analytical Instruments Manufacturers Association Medical devices committee (JAIMA)</td>
<td>Automatic clinical chemical analysis devices, blood test devices, laboratory devices, etc.</td>
<td>Sakura Building 3F, 1-10-1 Kandanishiki-cho, Chiyoda-ku, 101-0054&lt;br&gt;Phone: +81 3 3292 3450</td>
</tr>
<tr>
<td>Japan Contact Lens Association (Contact)</td>
<td>Contact lenses, maintenance goods for contact lenses, etc.</td>
<td>Yushima Bea Building 6F, 2-31-24 Yushima, Bunkyo-ku, 113-0034&lt;br&gt;Phone: +81 3 5802 5361</td>
</tr>
</tbody>
</table>
Legislative and Enforcement Processes and Types of Pharmaceutical Affairs-related Information

Table 3-2. List of Organizations Related to Medical Devices (Cont’d.)

<table>
<thead>
<tr>
<th>Name of Organization (abbreviation)</th>
<th>Major Product Lines/Businesses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Web Address</td>
<td>Address/Phone Number</td>
</tr>
<tr>
<td>Japan Industries Association of Physical Therapy Device (JIAPTD)</td>
<td>Low-frequency electric therapy equipment, thermal therapy equipment, massage equipment, traction equipment, etc.</td>
</tr>
<tr>
<td>Japan Ophthalmic Instruments Association (JOIS)</td>
<td>Ophthalmic examination equipment, ophthalmic surgery equipment, etc.</td>
</tr>
<tr>
<td>Japan Home Health Care Association (JHHC)</td>
<td>Home health care devices, nursing-care equipment, welfare equipment, etc.</td>
</tr>
<tr>
<td>Japan Hearing Instruments Manufacturers Association (JHIMA)</td>
<td>Hearing Instruments</td>
</tr>
<tr>
<td>Commercial and Industrial Association, Tokyo Medical Devices Association (TMDA)</td>
<td>Examination/diagnostic devices, disposable products, laboratory instruments, general medical devices/equipment, consulting, etc.</td>
</tr>
<tr>
<td>Japan Hearing Instruments Dispensers Association (JHIDA)</td>
<td>Marketing of hearing instruments</td>
</tr>
<tr>
<td>Japan Hygiene Products Industry Association (JHPIA)</td>
<td>Medical cotton, medical gauze, menstrual sanitary tampons, medical paper sheets, band-aids, etc.</td>
</tr>
<tr>
<td>Japan Contact Lens Association (Contact lens)</td>
<td>Contact lenses, etc.</td>
</tr>
<tr>
<td>Japanese Association of Surgical Sutures (JASS)</td>
<td>Surgical sutures, surgical sutures with attached needles, surgical suture needles, etc.</td>
</tr>
<tr>
<td>Japan Condoms Industrial Association (Condoms Industrial)</td>
<td>Male and female condoms</td>
</tr>
</tbody>
</table>

(As of August 2009, from the Japan Federation of Medical Devices Association website)

Some examples of announcements related to medical devices based upon the Pharmaceutical Affairs Law are described below.

Highly Controlled Medical Devices, Controlled Medical Devices, and General Medical Devices specified by the Minister of Health, Labour and Welfare has Specified Standards based on the provisions of Article 2, Paragraphs 5 to 7 of the Pharmaceutical Affairs Law (Ministry of Health, Labour and Welfare Announcement No. 298, Heisei 16 (2004))

issues to the public. This includes announcements of the Cabinet, Cabinet Office, various ministries, various committees, the courts, etc.

Although there are some cases in which an announcement method is specified in the laws and ordinances, such as “the Minister of XX must issue an announcement in a public bulletin of XX,” announcements from administrative institutions on other matters also are generally issued through public bulletins.
As indicated by the title, these announcements are specified by Article 2 (Definitions), Paragraph 5 of the Pharmaceutical Affairs Law, which states, “The term 'advanced managed-care devices' in this law [...] refers to those specified by the Minister of Health, Labour and Welfare after hearing the opinions of the Pharmaceutical Affairs and Food Hygiene Council.”

Maintenance Control Medical Devices, Controlled Medical Devices, General Medical Devices specified by the Minister of Health, Labour and Welfare based on the provisions of Article 2, Paragraph 8 of the Pharmaceutical Affairs Law (Ministry of Health, Labour and Welfare Announcement No. 298, Heisei 16 (2004))

As indicated by the title, these announcements are specified by Article 2 (Definitions), Paragraph 8 of the Pharmaceutical Affairs Law, which states, “The term ‘medical devices for maintenance management’ in this law [...] refers to those specified by the Minister of Health, Labour and Welfare after hearing the opinions of the Pharmaceutical Affairs and Food Sanitation Council.”


As indicated by the title, these announcements are specified by considering Article 41 (Japanese Pharmacopoeia, etc.), Paragraph 3 of the Pharmaceutical Affairs Law, which states, “The Minister of Health, Labour and Welfare may hear the opinions of the Pharmaceutical Affairs and Food Sanitation Council and establish necessary standards to ensure the properties, quality, and functions of medical devices.”

Examples of announcements issued after a ministerial ordinance include the following:

- **Medical devices specified by the Minister of Health, Labour and Welfare based on Article 4, Paragraph 1 of the Ministerial Ordinance on standards for manufacturing control and quality control of medical devices and in vitro diagnostics (Ministry of Health, Labour and Welfare Ordinance No. 439, Heisei 16 (2004))**

- **Ministerial Ordinance on QMS for Medical Devices and In Vitro Diagnosis (Applications):** “As items requiring management for design and development (hereinafter referred to as ‘design development’) for ensuring that manufacturing control and quality control for specific medical devices, etc. stipulated in Article 77-5, Paragraph 1 of the Law are appropriately implemented, products related to medical devices other than those specified by the Minister of Health, Labour and Welfare [...]”

### What Is a “Code?”

These are regulations for local public organizations and are determined at meetings of each local public organization. Codes are established within the scope of all laws and ordinances.

Article 3, Paragraph 2 of the Pharmaceutical Affairs Law provides stipulations regarding local pharmaceutical councils that “organize, operate and perform other necessary matters in relation to local pharmaceutical councils are stipulated in the provisions of such prefectural governments,” which corresponds to a “code.” Also, business-related fees, such as those related to manufacturing and marketing, are stipulated in the provisions of each prefectural government.

### What Are Messages (Notifications, Administrative Notices)?

These are formats for documents describing interpretations and operational policies for laws and ordinances for unified administration, as well as the use of authority. These are primarily issued by the central government to the prefectural governments. They are considered effective only within the receiving organizations, but are important when dealing with affairs related to understanding the application of law.

There are several notifications issued under the name of the director of PFSB as notifications related to drug products and medical devices, supplementary notifications issued under the name of the manager of the Compliance and Narcotics Division or the Office of Review Administration, and administrative notices indicating the administrative details from each division; these are also hierarchical.

The following are some examples of notifications along with descriptions of them.

Example: *Yakushokuhatsu* No.0508003 of May 8, Heisei 21 (2009) “Enforcement, etc. of laws, etc. that amend part of the Pharmaceutical Affairs Law”

In this case, “May 8, 2009” is the date the notification was issued.

“Yakushokuhatsu” indicates that the notice was issued by the director of the Pharmaceutical and Food Safety Bureau of MHLW. However, because job titles may be subject to change due to restructuring, they are not always the same. For example, notifications of 2002 issued by the director were indicated as “Iyakubussu,” and many such notifications are still in effect today.

The “0508” in “No. 0508003” indicates the date, and the following “003” shows the chronological order in which it was issued. This is because other notifications were issued on the same day. It should be noted that when specifying a notification, it is necessary to specify “*Yakushokuhatsu* No. 0508003” of which year, for example, because this “Yakushokuhatsu No. 0508003” does not include the year.
of issuance. In addition, for notifications issued after July of Heisei 21 (2009), the numerical notation has been changed to, e.g., “Yakushokukihatsu No. 0904-1.” However, the meanings of the numbers have not changed. Also, notifications issued before Heisei 13 (2001) do not follow this pattern; they indicate sequential numbers based upon years and job titles. In addition, supplementary Q&As, etc., for a notification are issued as administrative notices that do not have numbers but only the year and date of issuance.

Also, as is clear from the title, this is a notification on the “Enforcement, etc. of laws, etc. that amend part of the Pharmaceutical Affairs Law.”

As seen in this particular notification, it is addressed to the “governors of each prefecture, mayors of ordinance-designated cities, and mayors of special wards.” In this manner, notifications are published by MHLW to the local government, with specifically defined recipients for each notification type. The recipients of directorial notifications include the “governors of each prefecture, mayors of ordinance-designated cities, and mayors of special wards;” while the recipients of managerial notifications include “managers of prefectural public health offices;” and the recipients of administrative notices include the “pharmaceutical affairs divisions of prefectural public health offices.”

Following are more examples of the indication “XX Notification” of MHLW, indicating the source of the notification (in the current organization).

- MHLW hatsu iyaku—Message of the Vice Minister of the Ministry of Health, Labour and Welfare
- Yakushokubatsu—Notification of the Director of the Pharmaceutical and Food Safety Bureau
- Yakushokushinsahatsu—Notification of the Manager of the General Affairs Division of the Pharmaceutical and Food Safety Bureau
- Yakushokukanmahatsu—Notification of the Manager of the Compliance and Narcotics Division of the Pharmaceutical and Food Safety Bureau
- Yakushokuanhatsu—Notification of the Manager of the Safety Division of the Pharmaceutical and Food Safety Bureau
- Yakushokushinsahatsu—Notification of the Manager of the Office of Review Administration of the Pharmaceutical and Food Safety Bureau
- Yakushokukihatsu—Notification of the Director of the Office of Evaluation and Licensing of Medical Devices of the Pharmaceutical and Food Safety Bureau
- Yakushokushinsahatsu/Yakushokuanhatsu—Co-signed notification of the Managers of the Evaluation and Licensing Division and Safety Division of the Pharmaceutical and Food Safety Bureau
- Isihatsu—Notification of the Director of the Health Policy Bureau
- Isikeibatsu—Notification of the Manager of the Economic Affairs Division of the Health Policy Bureau
- Hobatsu—Notification of the Director of the Health Insurance Bureau
- Hoibatsu—Notification of the Manager of the Medical Economic Division of the Health Insurance Bureau

(In addition, Yakukihatsu are issued not by MHLW but under the name of the Chief Executive of PMDA.)

Sources of Information

Along with the promulgation of laws, government ordinances, provisions, etc., there are public bulletins, known as Kanpo (issued by the National Printing Bureau) of national institutes that publicize reports and materials and act as national newsletters and “publications for the people of Japan.”

Legal matters and government ordinances, ministerial ordinances, announcements, etc. are posted in the public bulletins. Laws enacted in Cabinet meetings and the provisions of amended laws are listed in the “Laws” section. When laws, government ordinances, provisions, etc. are promulgated in a public bulletin, an “Outline of laws and ordinances promulgated this issue” section follows the Contents section, and clearly summarizes the purpose and overview of newly enacted laws, government ordinances, provisions, etc. Categories include:

- “Public Bulletin (Kanpo),” National Printing Bureau
  This government bulletin is issued everyday on weekdays. Because laws and ordinances will be promulgated when published in a public bulletin, if the date of issuance or amendment is known, the subject laws and ordinances can be viewed by finding the public bulletin issued on that date.
- “Online Public Bulletin (Internet Kanpo),” National Printing Bureau [http://kanpou.npb.go.jp/]
  This bulletin is posted before noon and remains active for one week after posting. The National Printing Bureau website also has a Public Bulletin Information Search Service (members only, pay service) where one can search public bulletins issued after 3 May 1947 [http://kanpou.npb.go.jp/search/introduce.html].
- “Public Bulletin Reference (Kanpo Shiryo),” Office of the Prime Minister [http://www.kantei.go.jp/jp/kanpo-shiryo/index.html]
  Materials for governmental investigations issued as appendices to public bulletins after 6 August 1997 are available.
- “Public Bulletin Search (Kanpo Search)” (government-issued materials) [http://www.gov-book.or.jp/asp/Kanpo/KanpoList/]
  It is possible to search the contents for columns,
special editions, government procurement announcements and materials of public bulletins issued after 3 June 1996 (from the Government Data Research Center of Japan and the Osaka Prefectural Nakanoshima Library website).

For further details, please refer to Table 3-1, which shows sources of information and relevant website addresses for information related to pharmaceutical affairs administration, including the activities of regulatory agencies such as MHLW (councils and public comments), searches of law and ordinance databases and notifications and approval-related information. Table 3-2 lists organizations related to medical devices.

Summary
This chapter summarizes the general processes of enacting a law and the structure of the Pharmaceutical Affairs Law with regard to the “laws” that regulate the actions of the pharmaceutical industry. In addition, we have introduced the websites for public bulletins, MHLW, PMDA, prefectural governments, the Japan Association for the Advancement of Medical Equipment, industry groups, etc., as sources of new information related to the Pharmaceutical Affairs Law. Please visit and search these websites to obtain useful information.

References
6. Japan Federation of Medical Devices Association website (http://www.jfmda.gr.jp/)
7. All About website (http://allabout.co.jp/career/politicsabc/closeup/CU20080131B/)
8. TAXOTAK website (http://taxotak.livedoor.biz/archives/50165150.html)