Regulation for Enforcement of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices

医薬品、医療機器等の品質、有効性及び安全性の確保等に関する法律施行規則

Japan Ministry of Health, Labour and Welfare

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Regulation for Enforcement of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices

(Order of the Ministry of Health, Labour and Welfare No. 1 of February 1, 1961)

Based on the provisions of Articles 7 and 10 (including as applied mutatis mutandis pursuant to Articles 38 and 40), Article 14, paragraph (1) (including as applied mutatis mutandis pursuant to Article 23), Article 17, paragraph (1) (including as applied mutatis mutandis pursuant to Article 23), Article 19 (including as applied mutatis mutandis pursuant to Article 23), Article 21 (including as applied mutatis mutandis pursuant to Article 23), Article 29, Article 32, Article 33, paragraph (2), Article 39, paragraph (1), Article 43, paragraph (1), Article 44, paragraphs (1) and (2), Article 49, paragraph (2), Article 50, Article 52, and Article 53 (including as applied mutatis mutandis pursuant to Articles 60, 62 and 64) Articles 58, 59, 61, 63 and 82 of the Pharmaceutical Affairs Act (Act No. 145 of 1960), and Articles 2, 8, 9, 11, 15, and 16, and the row of Tools and Instruments, item (84) of Appended Table 1 of the Order for Enforcement of the Pharmaceutical Affairs Act (Cabinet Order No. 11 of 1961), the Regulation for Enforcement of the Pharmaceutical Affairs Act is hereby enacted as follows.

Chapter I Pharmacy

(Application for Establishment)

Article 1 (1) Written applications prescribed in Article 4, paragraph (2) of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (hereinafter called the "Act") are to be based on Form No. 1.

(2) Matters specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 4, paragraph (2), item (vi) of the Act are as follows:

(i) whether an applicant (including an officer in charge of operations if the applicant is a corporation) falls under any of Article 5, item (iii), (a) through (d) and (e) of the Act (excluding the part pertaining to a person who is addicted to narcotics, cannabis, opium, or stimulants);

(ii) normal business days and business hours;

(iii) the telephone number or other contact information for times of consultation and in emergencies;

(iv) whether specified sales (sales or provision of OTC pharmaceuticals or pharmacy-made pharmaceuticals (excluding any poisonous drugs and deleterious drugs; the same applies in paragraph (4), item (ii), (e) and Article 15-6) to persons at the pharmacy or at a pharmacy in a store or at a location other than the store; the same applies hereinafter) have been implemented.

(3) Criteria specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 4, paragraph (3), item (iv), (a) of the Act are as follows:

(i) pharmacy-only pharmaceuticals (excluding pharmacy-made pharmaceuticals);

(ii) pharmacy-made pharmaceuticals;

(iii) pharmaceuticals requiring guidance;

(iv) schedule I pharmaceuticals;

(v) designated schedule II pharmaceuticals (meaning schedule II pharmaceuticals designated by the Minister of Health, Labour and Welfare as requiring special care; the same applies hereinafter);

(vi) schedule II pharmaceuticals (excluding designated schedule II pharmaceuticals; the same applies in item (ii) of the following paragraph and Article 15-6, item (iii));

(vii) schedule III pharmaceuticals.

(4) Matters specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 4, paragraph (3), item (iv), (b) of the Act are as follows:
(i) the means of communication used in specified sales;
(ii) criteria for pharmaceuticals to be sold in specified sales set forth in (a) to (e) below:
(a) schedule I pharmaceuticals;
(b) designated schedule II pharmaceuticals;
(c) schedule II pharmaceuticals;
(d) schedule III pharmaceuticals;
(e) pharmacy-made pharmaceuticals;
(iii) in cases where there is the time for making specified sales or the time exclusively for making specified sales during business hours, the time;
(iv) in cases of labeling a name different from the name of the pharmacy indicated in a written application prescribed in Article 4, paragraph (2) of the Act in an advertisement for specified sales, the name;
(v) if specified sales are advertised on the Internet, a main web page address and summary of a main web page configuration;
(vi) a prefectural governor (if the location is in a city specified by Cabinet Order prescribed in Article 5, paragraph (1) of the Community Health Act (Act No. 101 of 1947) (hereinafter referred to as a "city with established health centers") or a special ward, the mayor of the city or the head of the special ward; the same applies in paragraph (6), Articles 6 and Article 15-6, item (iv)) or outline of the equipment required for the Minister of Health, Labour and Welfare to properly supervise the methods of carrying out specified sales (limited to cases where there is the time exclusively for making specified sales during the business hours of the pharmacy).

(5) Documents specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 4, paragraph (3), item (v) of the Act are as follows:
(i) a certificate of registered information in the case of a corporation;
(ii) documents including working hours per week (regular working hours per week) of a pharmacy manager (including a pharmacy proprietor responsible for practical management of the pharmacy pursuant to the provisions of Article 7, paragraph (1) of the Act; the same applies hereinafter except in the following item) and a registration number and a registration date of the register of pharmacists;
(iii) a copy of the employment agreement of a pharmacy manager and other documents proving an employment relationship between the applicant and the pharmacy manager, in cases where the pharmacy manager is designated for practical management of the pharmacy pursuant to the provisions of the proviso of Article 7, paragraph (1) of the Act or the provisions of Article 7, paragraph (2) of the Act;

ChemLinked Team | REACH24H Consulting Group| https://cosmetic.chemlinked.com
14th Floor, Building 3, Haichuang Technology Center, 1288 West Wen Yi Road, Hangzhou, China (311121)
Tel: +86 571 8700 7535 Fax: +86 571 8700 7566 Email: cosmetic@chemlinked.com

(iv) documents showing whether the person is a pharmacist or a registered sales clerk, working hours per week, and a registration number and a registration date of the register of pharmacists or those of the registration under Article 36-8, paragraph (2) of the Act (hereinafter referred to as the "sales engagement registration"), in cases of assigning a pharmacist or a registered sales clerk who engages in pharmaceutical practice at the pharmacy besides the pharmacy manager;

(v) a copy of an employment agreement of the pharmacist engaged in pharmaceutical practices or the registered sales clerk and other documents proving an employment relationship of applicant with the pharmacist or registered sales clerk, in cases of assigning a pharmacist or a registered sales clerk who engages in pharmaceutical practice at the pharmacy besides the pharmacy manager;

(vi) documents showing the average number of prescriptions handled per day (meaning the average number of prescriptions handled per day provided in Article 1, paragraph (1), item (ii) of the Ministerial Order to Determine the System for Pharmacies, Store-Based Distribution, and Household Distribution (Order of the Ministry of Health and Welfare No. 3 of 1964); the same applies hereinafter);

(vii) documents showing types of radioactive pharmaceuticals and the outline of equipment required to handle radioactive pharmaceuticals when the pharmacy intends to deal with radioactive pharmaceuticals (meaning radioactive pharmaceuticals provided in Article 1, item (i) of the Rules to Manufacture and Handle Radioactive Pharmaceuticals (Order of the Ministry of Health and Welfare No. 4 of 1961); the same applies hereinafter) (excluding the case where the pharmacy intends to handle radioactive pharmaceuticals below the quantity or concentration specified by the Minister of Health, Labour and Welfare);

(viii) documents showing types of operations undertaken at the pharmacy if selling pharmaceuticals or other businesses are also carried out there;

(ix) a doctor's written diagnosis with regard to mental impairment of the applicant (an officer responsible for the operation if the applicant is a corporation; the same applies in hereinafter in this item), or whether or not the applicant is addicted to narcotics, cannabis, opium, or stimulant.

(6) From among the documents set forth in each item of Article 4, paragraph (3) of the Act, those submitted to a prefectural governor who is in charge of receiving the written applications at the time of application or notification of license, etc. under the Act (hereinafter referred to as "applications and other acts") or submitted to the Minister of Health, Labour and Welfare via the prefectural governor are not required to be attached, if the written application has a supplementary note to that effect.

(7) The applicant may submit a document which shows the officer does not fall under Article 5, item (iii), (e) of the Act (except the part pertaining to adult wards; the same applies hereinafter) and (f) in place of a written diagnosis set forth in paragraph (5), item (ix) in cases where an applicant is a corporation, and a prefectural governor (in cases where the location is in a city with established health centers or a special ward, the mayor of the city or the head of the special ward) acknowledges the services are not adversely affected according to contents of the duties of the officer.

(8) The applicant is to present a registration certificate for completion of re-education prescribed in paragraph (3) of the same Article or attach its copy if a pharmacy manager is ordered by the Minister of Health, Labour and Welfare under Article 8-2, paragraph (1) of the Pharmacists Act (Act No. 146 of 1960) (hereinafter referred to as the "order for reeducation and training")

(Form for License Certificate for Establishing Pharmacies)

Article 2 A license certificate for establishing a pharmacy is to be based on Form No. 2.

(Display Form for License Certificate for Establishing Pharmacies)

Article 3 A pharmacy proprietor must display a license certificate for establishing a pharmacy at a readily visible place in the pharmacy.

(Written Application for Updated Issuance of License Certificate for Establishing Pharmacies)

Article 4 A written application for an updated issuance of a license certificate for establishing a pharmacy prescribed in Article 1-5, paragraph (2) of the Order for Enforcement of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (hereinafter referred to as the "Order") is to be based on Form No. 3.

(Written Application for Reissuance of License Certificate for Establishing Pharmacies)

Article 5 A written application for reissuance of a license certificate for establishing a pharmacy prescribed in Article 1-6 paragraph (2) of the Order is to be based on Form No. 4.

(Application for Renewal of License for Establishing Pharmacies)

Article 6 An applicant who intends to receive a renewal of a license certificate for establishing a pharmacy pursuant to the provisions of Article 4, paragraph (4) of the Act must submit a written application based on Form No. 5 with the license certificate for establishing a pharmacy to a prefectural governor.

(Matters to Be Included in Registry of License for Establishing Pharmacies)

Article 7 Matters to be included in the registry of license under Article 4, paragraph (1) of the Act provided in Article 1-8 of the Order are as follows:

(i) the license number and date;

(ii) the name of a pharmacy proprietor (in the case of a corporation, its name; the same applies hereinafter) and address (in the case of a corporation, the location of its principal office; the same applies hereafter);

(iii) the name and location of the pharmacy;

(iv) normal business days and business hours;

(v) the telephone number or other contact information for times of consultation and in emergencies;

(vi) the name, address, and working hours per week of a pharmacy manager;

(vii) the name, address, and working hours per week of a pharmacist engaged in pharmaceutical practice or a registered sales clerk who works for the pharmacy other than the pharmacy manager, if any;

(viii) the average number of prescriptions handled per day;

(ix) types of radioactive pharmaceuticals at the time of handling them;

(x) types of operations undertaken at the pharmacy if selling pharmaceuticals or other businesses are also carried out there;

(xi) criteria for pharmaceuticals sold or provided at the pharmacy which are set forth in each item of Article 1, paragraph (3);

(xii) matters set forth in each item of Article 1, paragraph (4) when the pharmacy conducts specified sales (excluding the overview of the configuration of the main website; the same applies in Article 16-2, paragraph (1), item (iii)).

(Period Specified by Order of the Ministry of Health, Labour and Welfare Prescribed in Article 4, Paragraph (5), Item (iii), (a) and (b) of the Act)

Article 7-2 (1) The period specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 4, paragraph (5), item (iii), (a) of the Act is the period set forth in each of the following items in accordance with the criteria for pharmaceuticals set forth in the following items:

(i) new pharmaceuticals provided in Article 14-4, paragraph (1), item (i) of the Act: the investigation period provided in Article 14-4, paragraph (1), item (i) of the Act (the extended period if the period has been extended under paragraph (2) of the same Article);

(ii) pharmaceuticals that are obliged to receive an investigation regarding post-marketing safety for a person who has obtained a marketing approval as a condition for the approval based on the provisions of Article 79, paragraph (1) of the Act (excluding the early post-marketing phase vigilance

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CHEMLINKED.COM

14th Floor, Building 3, Haichuang Technology Center, 1288 West Wen Yi Road, Hangzhou, China (311121)
Tel: +86 571 8700 7535 / Fax: +86 571 8700 7566 / E-mail: cosmetic@chemlinked.com
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