Order 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令

Japan Ministry of Health, Labour and Welfare

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

(Cabinet Order No. 11 of January 26, 1961)

The Cabinet hereby enacts this Cabinet Order pursuant to the provisions of Article 2, paragraph (4), Article 11 (including as applied mutatis mutandis pursuant to Article 38), Article 28, paragraph (2), Article 30, paragraph (3), Article 43, paragraph (2), Article 67, paragraph (1), Article 77, paragraph (3), Article 78, paragraph (1), Article 80 and Article 82 of the Pharmaceutical Affairs Act (Act No. 145 of 1960).

Chapter I General Provisions

(Scope of Medical Devices)

Article 1 Medical devices prescribed in Article 2, paragraph (4) of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (hereinafter referred to as the "Act") are as in appended table 1.

(Scope of Regenerative Medicine Products)

Article 1-2 Regenerative medicine products prescribed in Article 2, paragraph (9) of the Act are as in appended table 2.

Chapter II Pharmacies

(Laws and Regulations Specified by Cabinet Order Prescribed in Article 5, Item (iii), (d) of the Act)

Article 1-3 The laws and regulations specified by Cabinet Order prescribed in Article 5, item (iii), (d) of the Act are as follows:

(i) Cannabis Control Act (Act No. 124 of 1948);

(ii) Stimulants Control Act (Act No. 252 of 1951);

(iii) Opium Control Act (Act No. 71 of 1954);

(iv) Act on Securing a Stable Supply of Safe Blood Products (Act No. 160 of 1956);

(v) Pharmacists Act (Act No. 146 of 1960);

(vi) Act on Control of Household Products Containing Harmful Substances (Act No. 112 of 1973);

(vii) Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Act No. 117 of 1973);

(viii) Act Concerning Special Provisions for the Narcotics and Psychotropics Control Act, etc. and Other Matters for the Prevention of Activities Encouraging Illicit Conduct and Other Activities Involving Controlled Substances through International Cooperation (Act No. 94 of 1991);

(ix) Act on the Pharmaceuticals and Medical Devices Agency (Act No. 192 of 2002);

(x) Act on the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (Act No. 97 of 2003);

(xi) Act on Securing Safety of Regenerative Medicine (Act No. 85 of 2013).

(Issuance of License Certificate for Establishing Pharmacies)

Article 1-4 The prefectural governor (or the mayor of the city where the pharmacy is located (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 the head of the

special ward (hereinafter the same applies in this Chapter)) must, when granting the license for establishing a pharmacy, issue a license certificate to the applicant for the license, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare. The same applies when renewing a license for establishing a pharmacy.

(Updated Issuance of License Certificate for Establishing Pharmacies)

Article 1-5 (1) When any pharmacy proprietor (referring to pharmacy proprietors provided in Article 1-4 of the Act; hereinafter the same applies) encounters any change in matters stated in the license certificate for establishing a pharmacy, the pharmacy proprietor may apply for an updated issuance of the license certificate reflecting the change.

(2) The application under the preceding paragraph must be made by submitting a written application with a license certificate to the governor of the prefecture where the pharmacy is located, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Reissuance of License Certificate for Establishing Pharmacies)

Article 1-6 (1) Proprietors of pharmacies may, in the event of tearing, dirtying or loss of a license certificate for establishing pharmacies, apply for the reissuance of the license certificate.

(2) The application under the preceding paragraph must be submitted to the governor of the prefecture where such pharmacy is located, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare. In this case, any pharmacy proprietor who tore or dirtied a license certificate must attach the license certificate to the written application.

(3) Pharmacy proprietors must, when finding the lost license certificate for establishing pharmacies after having the license certificate reissued, promptly return such license certificate to the governor of the prefecture where the pharmacy is located.

(Return of License Certificate for Establishing Pharmacies)

Article 1-7 Pharmacy proprietors must, when they are subject to a disposition to rescind the license for establishing pharmacies under Article 75, paragraph (1) of the Act, or when they discontinue their operations, promptly return the license certificate for establishing pharmacies to the governor of the prefecture where such pharmacy is located.

(Registry of License for Establishing Pharmacies)

Article 1-8 The prefectural governors are to keep a registry of license prescribed in Article 4, paragraph (1) of the Act, stating necessary matters in such

registry, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Notification of the Number of Prescriptions Dispensed)

Article 2 Pharmacy proprietors must, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, notify the governor of the prefecture where such pharmacy is located of the total number prescriptions dispensed during the previous year (referring to the total number of prescriptions for othinolaryngology, ophthalmology and dentistry dispensed during the previous year, multiplied by two thirds, respectively, plus the number of prescriptions for the other departments; hereinafter the same applies in this Article) by March 31 of every year; provided, however, that this does not apply to cases where the total number of prescriptions dispensed is significantly small, as well as any other case specified by Order of the Ministry of Health, Labour and Welfare as equivalent to the preceding case.

(Delegation to Ministerial Order)

Article 2-2 Beyond what is specified in this Chapter, any necessary matters pertaining to pharmacies are specified by Order of the Ministry of Health, Labour and Welfare.

Chapter III Marketing and Manufacturing of Pharmaceuticals, Quasi-Pharmaceutical Products and Cosmetics

(Valid Term for Marketing Licenses)

Article 3 The valid term specified by Cabinet Order prescribed in Article 12, paragraph (2) of the Act is five years; provided, however, with regard to a license pertaining to marketing of pharmacy-made pharmaceuticals (referring to pharmaceuticals manufactured by a pharmacy proprietor using equipment and instruments in the pharmacy, and directly sold or provided to customers at the pharmacy (excluding in-vitro diagnostics; hereinafter the same applies in this Chapter) which do not contain any active components but active components designated by the Minister of Health, Labour and Welfare; hereinafter the same applies), the term specified by Cabinet Order prescribed in the same paragraph is valid for six years.

(Issuance of License Certificate for Marketing)

Article 4 (1) The Minister of Health, Labour and Welfare must, when granting a license for marketing pharmaceuticals, quasi-pharmaceutical products, or cosmetics, issue a license certificate to the applicant for such license, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare. The

same applies when renewing a license for marketing pharmaceuticals, quasi-pharmaceutical products, or cosmetics.

(2) In the application in the provisions of the preceding paragraph, when the prefectural governor (or the mayor of the city or special ward when a pharmacy marketing pharmacy-made pharmaceuticals is located in a city with established heath centers or a special ward; hereinafter the same applies in paragraph (4) of the following Article, Article 6, paragraph (5), Article 7, paragraph (2), Article 8, paragraph (2) and Article 19, paragraph (2)) is to grant a license for marketing pharmacy-made pharmaceuticals, pursuant to the provisions of Article 80, paragraph (1) (limited to the part pertaining to item (i)), "the Minister of Health, Labour and Welfare" in the same paragraph is to be replaced with "the prefectural governor (or the mayor of the city or special ward when a pharmacy marketing pharmacy-made pharmaceuticals is located in a city with established heath centers or a special ward)".

(3) In the application in the provisions of paragraph (1), when the prefectural governor is to grant a license for marketing pharmaceuticals, quasi-pharmaceutical products, or cosmetics provided in Article 80, paragraph (2), item (i), pursuant to the provisions of Article 80, paragraph (2) (limited to the part pertaining to item (i)), "the Minister of Health, Labour and Welfare" in the same paragraph is to be replaced with "the prefectural governor".

(Updated Issuance of License Certificate for Marketing)

Article 5 (1) If a change occurs in the matters described on the license certificate for marketing pharmaceuticals, quasi-pharmaceutical products, or cosmetics, holders of marketing authorization for pharmaceuticals, quasi-pharmaceutical products, or cosmetics may apply for an updated issuance of the license certificate to reflect the change.

(2) In the application under the preceding paragraph, a written application must be submitted to the Minister of Health, Labour and Welfare with a license certificate via the governor of the prefecture where the applicant resides (in the case of a corporation, where the principal office is located; hereinafter the same applies in the following Article and Article 7), pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(3) When an application under paragraph (1) is made, a fee specified by Cabinet Order after taking into consideration the actual costs must be paid.

(4) In the application in the preceding two paragraphs, in the case where the prefectural governor is to grant a license for marketing pharmacy-made pharmaceuticals, pursuant to the provisions of Article 80, paragraph (1) (limited to the part pertaining to item (i)), "to the Minister of Health, Labour and Welfare via the governor of the prefecture where the applicant resides (in the case of a corporation, where the principal office is located; hereinafter the

same applies in the following Article and Article 7)" in paragraph (2) is to be replaced with "the governor of the prefecture where the office for business engaged in by a marketing director of pharmaceuticals, quasi-pharmaceutical products or cosmetics provided in Article 17, paragraph (2) of the Act is located (or when the place is located in a city with established health centers or a special ward, the mayor of the city or the special ward)", and "a fee specified by Cabinet Order after taking into consideration the actual costs" in the preceding paragraph is to be replaced with "pursuant to the provisions of Prefectural Ordinance or Municipal Ordinance, pursuant to the provisions of Article 227 of the Local Autonomy Act (Act No. 67 of 1947)".

(5) In the application in the provisions of paragraph (2) and paragraph (3), in the case where the prefectural governor is to grant a license for marketing pharmaceuticals, quasi-pharmaceutical products, or cosmetics provided in Article 80, paragraph (2), item (i), pursuant to the provisions of Article 80, paragraph (2) (limited to the part of item (i)), "the Minister of Health, Labour and Welfare via the governor of the prefecture where the applicant resides (in the case of a corporation, where the principal office is located; hereinafter the same applies in the following Article and Article 7)" in paragraph (2) is to be replaced with "the governor of the prefecture where the office for business engaged in by a marketing director of pharmaceuticals, quasi-pharmaceutical products or cosmetics provided in Article 17, paragraph (2) of the Act is located", and "a fee specified by Cabinet Order after taking into consideration the actual costs" in paragraph (3) is to be replaced with "pursuant to the provisions of Prefectural Ordinance or Municipal Ordinance, pursuant to the provisions of Article 227 of the Local Autonomy Act (Act No. 67 of 1947)".

(Reissuance of License Certificate for Marketing)

Article 6 (1) If tearing, dirtying or losing a license certificate for marketing pharmaceuticals, quasi-pharmaceutical products, or cosmetics, holders of marketing authorization for pharmaceuticals, quasi-pharmaceutical products, or cosmetics may apply for reissuance of the license certificate.

(2) The application under the preceding paragraph must be submitted to the Minister of Health, Labour and Welfare via the governor of the prefecture where the applicant resides, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare. In this case, any holder of marketing authorization for pharmaceuticals, quasi-pharmaceutical products, or cosmetics who tore or dirtied a license certificate must attach such license certificate to the written application.

(3) A person making an application under paragraph (1) must pay a fee specified by Cabinet Order after taking into consideration the actual costs.

(4) Holders of marketing authorization for pharmaceuticals, quasi-

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