

The Ministry of Health, Labour and Welfare Ministerial Notification No. 111

Pursuant to Paragraph 1, Article 41 of the Pharmaceutical Affairs Law (Law No. 145, 1960), the Japanese Pharmacopoeia (hereinafter referred to as the “new Pharmacopoeia”), which has been established as follows*, shall be applied on April 1, 2001, and the Ministry of Health and Welfare Ministerial Notification No. 73 (Matter of Establishing the Japanese Pharmacopoeia Pursuant to the Provisions of the Pharmaceutical Affairs Law; hereinafter referred to as the “previous Pharmacopoeia”), issued in March 1996, shall be abolished on March 31, 2001. However, in the case of drugs which are listed in the new Pharmacopoeia (limited to those listed in the previous Pharmacopoeia) and drugs which have been approved as of April 1, 2001 as prescribed under Article 14 of the same law [(including cases where it applies mutatis mutandis under Article 23 of the same law; the same hereinafter) (including drugs the Minister of Health, Labour and Welfare specifies (the Ministry of Health and Welfare Ministerial Notification No. 104, March 1994) as those exempted from manufacturing or import approval pursuant to Paragraph 1, Article 14 of the Pharmaceutical Affairs Law (hereinafter referred to as “drugs exempted from approval”)), the Standards established in the previous Pharmacopoeia (limited to part of the Standard for the drugs concerned) may be accepted to conform to the Standards established in the new Pharmacopoeia before and on September 30, 2002. In the case of drugs which are listed in the new Pharmacopoeia (excluding those listed in the previous Pharmacopoeia) and drugs which have been approved as of April 1, 2001 as prescribed under Article 14 of the same law (including those exempted from approval), they may be accepted as those being not listed in the new Pharmacopoeia before and on September 30, 2002.

Chikara Sakaguchi

The Minister of Health, Labour and Welfare

March 30, 2001

(The texts referred to by the term “as follows” are omitted here. All of them are made available for public exhibition at the Ministry of Health, Labour and Welfare and at each Prefectural Office in Japan.)

*The word “follows” here refers to the text from “The Japanese Pharmacopoeia Fourteenth Edition, Part I” up to “Ultraviolet-visible Reference Spectra, Part II” (pp. 1-1302).