New Regulations of Non-Corrective Colored Contact Lenses under the Pharmaceutical Affairs Law

I. Defining the Product as "Medical Devices" under the Pharmaceutical Affairs Law

Articles individually specified by the relevant Cabinet Order are regulated as "medical devices" under the Pharmaceutical Affairs Law of Japan (hereinafter referred to as the "Law").

MHLW decided to regulate non-corrective colored contact lenses (hereinafter referred to as "non-corrective contact lenses") in a similar manner as corrective contact lenses. The Cabinet Order listing the devices was amended and "contact lenses (excluding those intended to correct eyesight)" was added as a "medical device" regulated under the Law. The thus revised Cabinet Order was promulgated on February 4, 2009 and came into effect on November 4, 2009, nine months after the date of promulgation.

II. Summary of Regulations of Non-corrective Colored Contact Lenses as Medical Devices and Interim Measures

1. Regulations for non-corrective contact lenses

(1) Handling of non-corrective contact lenses already shipped at the time of enforcement of the Cabinet Order

The following interim measures were taken for non-corrective contact lenses already shipped in Japan (hereinafter referred to as "stock in store") at the time of the enforcement.

1) Exemption of labeling on the immediate container and package insert

The legal requirements to indicate necessary information on the immediate container and package insert were exempted.

2) Exemption from prohibition of advertisement of unapproved medical devices

The prohibition of advertisement of medical devices which have not been approved by the Minister of Health, Labour and Welfare was exempted.

3) Interim measures regarding sales

a. A retailer is allowed to sell existing non-corrective contact lenses for a period of three months after the Cabinet Order was enforced.

b. Non-corrective contact lenses which do not meet the standards shall not be sold after three months from the enforcement.

(2) Non-corrective contact lenses to be manufactured and marketed within 12 months from the date of enforcement of the Cabinet Order (November 4, 2009)

1) Temporary exemption of approval, notification and labeling

Non-corrective contact lenses that conform to the relevant quality assurance standards specified separately and of which the notification for marketing was submitted to the Minister of Health, Labour and Welfare by the manufacturer shall be exempted from the duties to obtain marketing approval of the Minister of Health, Labour and Welfare. Such exemption is effective for one year (up to November 3, 2010) for their manufacture/sales, and for one year and three months (up to February 3, 2011) for their sales.

2) Exemption from prohibition of advertisement of unapproved medical devices

Same as the above (1)-2).

(3) Non-corrective contact lenses to be manufactured and marketed after one year from the date of enforcement of the Cabinet Order (November 4, 2009)

No exceptional interim measures are taken.

2. Regulations on business license

(1) License for marketing authorization holder

1) Duties of marketing authorization holder

Since the date of enforcement of the Cabinet Order (November 4, 2009), only marketing authorization holders (MAHs) have been allowed to market non-corrective contact lenses. MAHs is required to fulfill the following duties: Conformance to the Good Quality Practice (GQP), conformance to the Good Vigilance Practice (GVP), appointment of a marketing supervisor-general, provision of information to the retailers and healthcare professionals, report of adverse events, etc.

2) Interim measures for qualifications of marketing supervisor-general

A MAH is required by law to appoint a marketing supervisor-general, a quality assurance supervisor, and a safety management supervisor, who fulfill the legal qualifications, such as having practical job experience.

Among the qualifications of these supervisors, that to have practical job experience is deemed fulfilled by taking a “special training course” when the MAH intends to market non-corrective contact lenses alone.

(2) License for manufacturer and accreditation of foreign manufacturer

1) Duties of domestic or foreign manufacturer

Since the date of enforcement of the Cabinet Order (November 4, 2009), domestic manufacturers and foreign manufacturers have been required to obtain “license for

manufacturer" and "accreditation of foreign manufacturer," respectively, for manufacturing non-corrective contact lenses. Both manufacturers are required to conform to the Quality Management System (QMS), to appoint a responsible engineering supervisor, to maintain manufacturing and testing records, etc.

2) Interim measures for qualifications of responsible engineering supervisor

A medical device manufacturer is required by law to appoint a "responsible engineering supervisor" who fulfills the legal qualifications, such as having practical job experience.

Among the qualifications of the responsible engineering supervisor, that to have practical job experience is deemed fulfilled by taking a "special training course" when the manufacturer intends to manufacture non-corrective contact lenses alone.

(3) License for retailer

1) Duties of retailer

Since the date of enforcement of the Cabinet Order (November 4, 2009), retailers have been required to obtain "license for retailer" for selling non-corrective contact lenses. Retailers are required to appoint a responsible supervisor, to provide information to the purchasers or users, etc.

2) Interim measures for qualifications of supervisor

A retailer is required by law to appoint a responsible supervisor who fulfills the legal qualifications, such as having practical job experience.

Among the qualifications of the responsible supervisor, that to have practical job experience is deemed fulfilled by taking a "special training course" when the retailer intends to sell non-corrective contact lenses alone.

Transitional Measures for Non-Corrective Colored Contact Lenses