

Tentative translation VER. 1¹

MHLW Ministerial Ordinance No. 136, 2004

In accordance with the provision of Item (1) of Article 12-2 of Pharmaceutical Affairs Law (Law No. 145, 1960), MHLW Ministerial Ordinance on Standards for Quality Assurance for Drugs, Quasi-drugs, Cosmetics and Medical Devices is established as follows.

22 September 2004

Chikara SAKAGUCHI
Minister of Health, Labour and Welfare

Ministerial Ordinance on Standards for Quality Assurance for Drugs, Quasi-drugs, Cosmetics and Medical Devices

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Supplementary Provision

¹ Note/ This is a tentative translation of afore-mentioned Ordinance in English which is not an authentic and not formally authorised by Ministry of Health, Labour and Welfare of Japan.

Chapter 1 General Provisions

(Purpose)

Article 1 This Ministerial Ordinance shall provide the standards in accordance with Item (1) of Article 12-2 of the Pharmaceutical Affairs Law (Law No. 145, 1960) (hereinafter referred to as “Law”) which provides that such standards shall be provided by the MHLW Ministerial Ordinance.

(Definitions)

Article 2 “**Quality assurance duty**” throughout this Ministerial Ordinance means the duty necessary, in case where the drugs (excluding active pharmaceutical ingredients, and hereinafter referred to as such), quasi-drugs, cosmetics or medical devices (hereinafter referred to as “drugs, etc.”) are marketed, for ensuring quality of the products (including the intermediate products that have undergone the intermediate process and need to undergo subsequent process to be the (final) products, and hereinafter referred to as such) including: controlling market release of the drugs, etc.; supervising the manufacturers, foreign manufacturers specified in Paragraph 1 of Article 13-3 of Law (hereinafter referred to as “foreign manufacturers”) and other organisations who conduct the duties concerned with the manufacturing (including testing, etc.) (hereinafter referred to as “manufacturers, etc.”); handling the information on the quality, etc. and the quality defects, etc.; handling recall; and other duties necessary for controlling the quality of the products.

2. “**Market release**” throughout this Ministerial Ordinance means releasing the drugs, etc. that are manufactured (including the case where the manufacturing of own products is outsourced to an external organisation, but excluding the case where the contracted products are manufactured by the marketing authorisation holder under a contract with an external organisation, and hereinafter referred to as such) or imported for the purpose of marketing.
3. “**Lot**” throughout this Ministerial Ordinance means a grouping of the products that are manufactured so as to have a uniform quality in a series of the manufacturing process for a certain manufacturing period.
4. “**Cell/tissue-based drug**” throughout this Ministerial Ordinance means the drug composed of human or animal cells or tissue (excluding human blood and the drugs which compose of the components manufactured using human blood).
5. “**Cell/tissue-based medical device**” throughout this Ministerial Ordinance means the medical device composed of human or animal cells or tissue.

Chapter 2 Standards for Quality Assurance for Drugs

(Duties of General Marketing Manager)

Article 3 The marketing authorisation holder of drugs shall have the general marketing manager specified in Paragraph 2 of Article 17 of Law (hereinafter referred to as “general marketing manager”) conduct the following duties.

- (1) To supervise the quality assurance manager specified in Paragraph 3 of next

Article,

- (2) To determine necessary measures, in addition to those specified in Item (2) of Paragraph 2 of Article 11, based on the reports from the quality assurance manager specified in preceding Item (1), and to instruct the quality assurance department specified in Paragraph 2 of next Article and other departments or responsible persons concerned with the quality assurance duties to take such measures,
- (3) To respect the opinions of the quality assurance manager specified in preceding Item (1), and
- (4) To have the quality assurance department specified in preceding Item (2) closely collaborate with the safety control management department specified in Paragraph 1 of Article 4 of the Ministerial Ordinance on Standards for Post-marketing Safety Management for Drugs, Quasi-drugs, Cosmetics and Medical Devices (MHLW Ministerial Ordinance No. 135, 2004, and hereinafter referred to as “Standards for Post-marketing Safety Management”), (for the marketing authorisation holder of drugs other than those specified in Paragraph 1 of Article 49 of Law, with the safety control manager specified in Paragraph 2 of Article 13 of Standards for Post-marketing Safety Management (hereinafter referred to as “safety control management department” in this Chapter)), and with other departments concerned with the quality assurance duties.

(Organisation and Personnel for Quality Assurance Duties)

Article 4 The marketing authorisation holder of drugs shall have a sufficient number of personnel who have competence for conducting the quality assurance duties properly and efficiently.

2. The marketing authorisation holder of drugs shall establish a quality assurance department that supervises the quality assurance duties and meets the following requirements (hereinafter referred to as the “quality assurance department” in this Chapter).
 - (1) To be supervised by the general marketing manager,
 - (2) To have a sufficient number of personnel who have competence for conducting the duties assigned to the quality assurance department properly and efficiently, and
 - (3) To be independent of any department engaged in the sales of the drugs, etc. and any other department that affects proper and efficient conduct of the quality assurance duties.
3. The marketing authorisation holder of drugs shall assign a responsible person in charge of the quality assurance duties who meets the following requirements (hereinafter referred to as “quality assurance manager” in this Chapter).
 - (1) To be the responsible person in charge of the quality assurance department,

- (2) To be the person who has engaged in the quality assurance duties or other similar duties for at least three years,
 - (3) To be the person who has competence for conducting the quality assurance duties properly and efficiently, and
 - (4) Not to be the person who belongs to the department engaged in the sales of the drugs, etc. nor who could hinder the proper and efficient conduct of the quality assurance duties.
4. The marketing authorisation holder of drugs shall define and document properly the scope of responsibilities of the personnel engaged in the quality assurance duties (including the general marketing manager and the quality assurance manager, and hereinafter referred to as such), and the system for supervising them.

(Quality Standard Code)

Article 5 The marketing authorisation holder of drugs shall establish, for each of the drugs, documents which describe the items of the marketing approval of the drugs and other necessary items concerned with the quality of the drugs (hereinafter referred to as “quality standard code”).

(Quality Assurance Duty Procedure Documents)

Article 6 The marketing authorisation holder of drugs shall establish documents for the following procedures for proper and efficient conduct of the quality assurance duties (hereinafter referred to as “quality assurance duty procedure documents” in this Chapter).

- (1) The procedure for controlling market release,
- (2) The procedure for ensuring the proper manufacturing control and quality control,
- (3) The procedure for handling the information on quality, etc. and quality defects, etc.,
- (4) The procedure for handling recall,
- (5) The procedure for the self-inspections,
- (6) The procedure for the training,
- (7) The procedure for controlling the storage, etc. of the drugs,
- (8) The procedure for controlling the documents and records,
- (9) The procedure for the mutual collaboration among the departments or responsible persons concerned with the quality assurance duties including the safety control management department, and
- (10) Other necessary procedures for proper and efficient conduct of the quality assurance duties.

2. The marketing authorisation holder of drugs shall place the quality standard code specified in preceding Article and the quality assurance duty procedure documents specified in preceding Paragraph 1 (hereinafter referred to as “quality assurance duty procedure documents, etc.” in this Chapter) in the office where the general marketing manager conducts his/her duties, and also place copies thereof in other offices where the quality assurance duties are conducted.

(Contract with Manufacturers, etc.)

Article 7 The marketing authorisation holder of drugs shall conclude a contract for the following items with the manufacturers, etc. of the products and describe the details of the agreement in the quality assurance duty procedure documents, etc. to ensure that the manufacturing control and quality control are conducted properly and efficiently by the manufacturers, etc.

- (1) The scope of the manufacturing and other duties concerned with the manufacturing conducted by the manufacturers, etc. (hereinafter referred to as “manufacturing duties” in this Chapter), and the procedure for the manufacturing control, quality control and shipment concerned with the manufacturing duties,
- (2) The technical requirements for the manufacturing procedure, testing procedure, etc.,
- (3) The nature and extent of the periodical verification, by the marketing authorisation holder, of the manufacturing duties that they are conducted under the proper and efficient manufacturing control and quality control,
- (4) The procedures of the quality control during the transportation and delivery of the products,
- (5) The procedures and the responsible persons to communicate, in advance, any change in the manufacturing procedure, testing procedure, etc. to the marketing authorisation holder, in case where such a change could affect the quality of the products,
- (6) The procedures and the responsible persons to promptly communicate the following information on the products obtained by each of the manufacturers, etc. to the marketing authorisation holder, and
 - a. Information on the discontinuance of the manufacturing, import or distribution of the products, or the recall, disposal or other actions taken for the products to prevent jeopardising the public health and hygiene, and
 - b. Other information on the quality, etc. of the products.
- (7) Other necessary items.

(Duties of Quality Assurance Manager)

Article 8 The marketing authorisation holder of drugs shall have the quality assurance manager conduct the following duties in accordance with the quality assurance duty

procedure documents, etc.

- (1) To supervise the quality assurance duties,
- (2) To verify that the quality assurance duties are conducted properly and efficiently,
- (3) To report in writing whatever necessary for conducting the quality assurance duties to the general marketing manager, in addition to those reported to him/her in accordance with the provisions of Item (3)c. of Paragraph 5 of Article 9, Item (3) of Paragraph 2 of Article 10, Item (4) of Paragraph 1 of Article 11, Items (1) and (5) of Paragraph 2 of Article 11, Item (2) of Article 12, and Paragraph 2 of Article 13, and
- (4) To communicate with or instruct in writing, where necessary, the manufacturers, etc., distributors, pharmacy proprietors, hospital proprietors, clinic proprietors and other parties concerned, when conducting the quality assurance duties.

(Control of Market Release)

Article 9 The marketing authorisation holder of drugs shall, in accordance with the quality assurance duty procedure documents, etc., ensure that the results of the manufacturing control and quality control are properly evaluated and that the decisions on market release are made properly and efficiently, and shall not allow the shipment of the drugs until the decisions are properly made.

2. The marketing authorisation holder of drugs shall, in accordance with the quality assurance duty procedure documents, etc., have the person designated beforehand in the quality assurance department or the manufacturers of the products properly evaluate the results of the manufacturing control and quality control, make decisions on market release for each lot (for each manufacturing number, in case where the drugs do not constitute a lot, and hereinafter referred to as such) and establish records of the results of the evaluation and decisions and records concerned with the market release including the shipping consignees.
3. The person who conducts the duties of making decisions on market release specified in preceding Paragraph 2 shall have competence for conducting the duties properly and efficiently.
4. The marketing authorisation holder of drugs shall, in case where any person other than the quality assurance manager makes decisions on market release, have the person report properly in writing the results of the decisions, to the quality assurance manager.
5. In case where the marketing authorisation holder of drugs has the manufacturers conduct the duties specified in Paragraph 2 of this Article, the following duties shall be fulfilled.
 - (1) To conclude a contract, in advance, with the manufacturers for the following items,
 - a. Establishing the procedure for controlling market release conducted by the manufacturers,

- b. Designating a person beforehand in the manufacturing site of the products who conducts the duties specified in Paragraph 2 of this Article,
 - c. Reporting promptly in writing, in case where any deviation from the procedure specified in preceding a. has occurred, the deviation to the quality assurance manager, and making decisions on market release and shipping the drugs to the market in accordance with the instructions of the quality assurance manager, by the manufacturers, and
 - d. Allowing the marketing authorisation holder to periodically verify that the manufacturers conduct the market release duties properly and efficiently.
- (2) To have the person designated beforehand in the quality assurance department conduct the verification specified in preceding Item (1)d. and establish records concerned with the results of the verification properly,
- (3) To have the quality assurance manager conduct the following duties in case where improvements are necessary for the market release duties conducted by the manufacturers, and
- a. Instructing in writing the manufacturers to take necessary actions,
 - b. Requesting the manufacturers to report the results of the actions taken, evaluating the results properly, conducting, where necessary, on-site verification of the manufacturing site and establishing records concerned with the results of the evaluation and verification, and
 - c. Reporting in writing the results of the evaluation and verification specified in preceding b. to the general marketing manager.
- (4) To have the person other than the quality assurance manager, in case where he/she conducts the verification and establishment of records specified in preceding Item (2), report in writing the results of the verification and establishment of records to the quality assurance manager.
6. The marketing authorisation holder of drugs shall properly provide the person who makes decisions on market release in accordance with the quality assurance duty procedure documents, etc. with the information on the quality, efficacy and safety of the drugs necessary for making the decisions properly and efficiently.

(Ensuring Proper Manufacturing Control and Quality Control)

Article 10 The marketing authorisation holder of drugs shall have the person designated beforehand in the quality assurance department conduct the following duties in accordance with the quality assurance duty procedure documents, etc.

- (1) To periodically verify that the manufacturing control and quality control by the manufacturers, etc. is conducted properly and efficiently in accordance with the standards and items specified in MHLW Ministerial Ordinances that are provided to be established under the provisions of Item (4) of Paragraph 2 of Article 14 and

Paragraph 2 of Article 18 of Law and in accordance with the contract specified in Article 7 of this Ministerial Ordinance, and to establish records regarding the results of the verification, and

- (2) To have the person other than the quality assurance manager, in case where he/she conducts the verification and establishment of records specified in preceding Item (1), report in writing the results of the verification and establishment of records to the quality assurance manager.
2. The marketing authorisation holder of drugs, in case where improvements are necessary for the manufacturing control and quality control conducted by the manufacturers, etc., shall have the quality assurance manager conduct the following duties in accordance with the quality assurance duty procedure documents, etc.
 - (1) To instruct in writing the manufacturers, etc. to take necessary actions,
 - (2) To request the manufacturers, etc. to report the results of the actions taken, to evaluate the results properly, to conduct, where necessary, on-site verification of the manufacturing site, etc. and to establish records concerned with the results of the evaluation and verification, and
 - (3) To report in writing the results of the evaluation and verification specified in preceding Item (2) to the general marketing manager.
3. The marketing authorisation holder of drugs, in case where he/she has been communicated by the manufacturers, etc. with any change in the manufacturing procedure, the testing procedure, etc. which could affect the quality of the products, shall have the person designated beforehand in the quality assurance department conduct the following duties in accordance with the quality assurance duty procedure documents, etc.
 - (1) To evaluate the details of the communication from the manufacturers, etc., to verify that the change does not seriously affect the quality of the products, to conduct, where necessary, on-site verification of the manufacturing site, etc. that the manufacturing control and quality control are conducted properly and efficiently, and to establish records concerned with the results of the evaluation, verification and establishment of records, and
 - (2) To have the person other than the quality assurance manager, in case where he/she conducts the evaluation, verification and establishment of records specified in preceding Item (1), report in writing the results of the evaluation, verification and establishment of records to the quality assurance manager.
4. The marketing authorisation holder of drugs, in case where he/she identifies that the change could seriously affect the quality of the products as the result of the evaluation specified in Item (1) of preceding Paragraph 3, shall have, in accordance with the quality assurance duty procedure documents, etc., the quality assurance manager instruct promptly in writing the manufacturers, etc. to take necessary actions including improvements, etc.

5. The marketing authorisation holder of drugs shall provide the manufacturers, etc. with the information on the quality of the drugs necessary for conducting the manufacturing control and quality control properly and efficiently.

(Handling Information on Quality, etc. and Quality Defects, etc.)

Article 11 The marketing authorisation holder of drugs shall, in case where he/she has received the information on the quality, etc. of the drugs (hereinafter referred to as “quality information” in this Chapter), have the quality assurance manager conduct the following duties in accordance with the quality assurance duty procedure documents, etc.

- (1) To examine the quality information and to evaluate properly the effects of the matters concerned with the quality information on the quality, efficacy and safety of the drugs and on the human health,
 - (2) To investigate the cause of the matters concerned with the quality information,
 - (3) To take necessary corrective actions in case where they are necessary for improving the quality assurance duties or the manufacturing control and quality control by the manufacturers etc. based on the results of the evaluation or investigation specified in preceding two Items (1) and (2),
 - (4) To establish records describing the details of the quality information, the results of the evaluation, the results of the investigation and the improvements specified in preceding three Items (1) to (3), and to promptly report in writing the records to the general marketing manager,
 - (5) To give instructions in writing to the manufacturers, etc., in case where they are necessary for the investigation specified in preceding Item (2) or the improvements specified in preceding Item (3), as well as to request the manufacturers, etc. to report in writing the results of the actions taken based on the instructions, to evaluate the results properly and to conduct, where necessary, on-site verification of the progress of the improvements made in the manufacturing sites, etc., and to establish records concerned with the results, and
 - (6) To provide promptly in writing the safety control management department with the quality information which is concerned with the measures to ensure safety specified in Paragraph 2 of Article 2 of Standards for Post-marketing Safety Management (hereinafter referred to as “measures to ensure safety”).
2. The marketing authorisation holder of drugs shall, in case where he/she has identified quality defects or their possibility as a result of the duties specified in preceding Paragraph 1, in accordance with the quality assurance duty procedure documents, etc., have the general marketing manager and the quality assurance manager conduct the following duties.
 - (1) To have the quality assurance manager report promptly the quality defects or their possibility to the general marketing manager and to establish records thereof,
 - (2) To have the general marketing manager, in case where he/she has received the

report specified in preceding Item (1), promptly make decisions on necessary actions including recall to prevent jeopardy, etc., and give instructions to the quality assurance manager and to other departments concerned,

- (3) To have the quality assurance manager, in case where he/she has received the instructions from the general marketing manager in accordance with the provision of preceding Item (2), promptly take the necessary actions,
- (4) To have the quality assurance manager closely collaborate with the safety control management department and other departments concerned to ensure that the actions specified in preceding Item (3) are taken properly and efficiently, and
- (5) To have the quality assurance manager report in writing the progress and the results of the actions taken specified in preceding Item (3) to the general marketing manager.

(Handling Recall)

Article 12 The marketing authorisation holder of drugs shall, in case where he/she conducts recall of the drugs, have, in accordance with the quality assurance duty procedure documents, etc., the quality assurance manager conduct the following duties.

- (1) To segregate the drugs recalled, and to dispose of them properly after storing for a certain period, and
- (2) To establish records describing the details of the recall, and to report in writing them to the general marketing manager.

(Self-inspections)

Article 13 The marketing authorisation holder of drugs shall, in accordance with the quality assurance duty procedure documents, etc., have the person designated beforehand conduct the following duties.

- (1) To conduct the self-inspections periodically on the quality assurance duties and to establish records of the results, and
 - (2) To have the person other than the quality assurance manager, in case where he/she conducts the duties specified in preceding Item (1), report in writing the results of the self-inspections to the quality assurance manager.
2. The marketing authorisation holder of drugs, in case where improvements are necessary based on the results of the self-inspections, shall have the quality assurance manager take necessary actions, establish records of the actions and report in writing the results of the actions to the general marketing manager.

(Training)

Article 14 The marketing authorisation holder of drugs shall have the person designated beforehand establish a plan of training for the personnel engaged in the quality assurance duties.

2. The marketing authorisation holder of drugs shall have, in accordance with the quality

assurance duty procedure documents and the plan of training specified in preceding Paragraph 1, the person designated beforehand conduct the following duties.

- (1) To implement as planned the training concerned with the quality assurance duties for the personnel engaged in the quality assurance duties, and to establish records of the implementation of the training, and
- (2) To have the person other than the quality assurance manager, in case where he/she conducts the duties specified in preceding Item (1), report in writing the progress of the training to the quality assurance manager.

(Control of Drug Storage, etc.)

Article 15 The marketing authorisation holder of drugs, in case where he/she stores or displays the drugs he/she manufactured, etc. or imported for the purpose of marketing, shall meet the following requirements.

- (1) To assign responsible persons in charge of the duties of storing or displaying the drugs, or
- (2) To ensure that the personnel engaged in the duties of storing or displaying the drugs, including the responsible persons, meet the following requirements,
 - a. Not belonging to the quality assurance department, and
 - b. Having competence necessary for conducting the duties, and having completed necessary training.
- (3) To be provided with the buildings and facilities that meet the following requirements in the office where the general marketing manager conducts his/her duties, and to maintain them properly, and
 - a. Being provided with the facilities necessary for storing the drugs sanitarily and safely,
 - b. Being ensured sufficient area necessary for conducting the operations properly and efficiently, and
 - c. Conforming to the provisions specified in Paragraphs 2, 3, and 4 of Article 1 of the Regulations for Buildings and Facilities of Pharmacies, etc. (MHW Ministerial Ordinance No.2, 1961) in case where he/she handles the radiopharmaceuticals. In this case, “dispensing rooms” in the provisions of Paragraphs 3 and 4 of Article 1 of the Regulations shall read “work rooms”.
- (4) To establish records concerned with the duties of storing or displaying the drugs including control of the receipt and delivery of the drugs.

(Control of Documents and Records)

Article 16 The marketing authorisation holder of drugs shall control the documents and records specified in this Chapter in accordance with the following requirements.

- (1) To approve, distribute, maintain, etc. the documents in case where they are established or revised in accordance with the quality assurance duty procedure documents,
- (2) To put the date of the establishment or the revision of the quality assurance duty procedure documents, etc. on them, and to maintain records of the history of previous revisions in case where they are established or revised, and
- (3) To maintain the documents and records specified in this Chapter for the following period from the date of the establishment (from the date when they fell into disuse, for the quality assurance duty procedure documents, etc.).
 - a. 30 years plus the shelf life or the period until the expiry date (hereinafter referred to as “shelf life”) for the specified biological-origin products specified in Paragraph 10 of Article 2 of Law (hereinafter referred to as “specified biological-origin products”) or for the biological-origin products specified in Paragraph 9 of Article 2 of Law manufactured using human blood as the origins of the raw materials (including those used in the manufacturing process, and hereinafter referred to as such) (hereinafter referred to as “human-blood-origin products”),
 - b. 10 years plus the shelf life for the biological-origin products specified in Paragraph 9 of Article 2 of Law (hereinafter referred to as “biological-origin products”), or for cell/tissue-based drugs (except for those listed in preceding a.),
 - c. 5 years for the drugs other than the biological-origin products or the cell/tissue-based drugs (1 year plus the shelf life for the drugs concerned with the documents and records of which shelf life plus 1 year exceeds 5 years), or
 - d. 5 years for the documents and records concerned with the training, notwithstanding the period specified in the provisions of preceding a., b. and c.

Chapter 3 Standards for Quality Assurance for Quasi-Drugs and Cosmetics

(Assignment of Quality Assurance Manager)

Article 17 The marketing authorisation holder of quasi-drugs and cosmetics (hereinafter referred to as “quasi-drugs, etc.” in this Chapter) shall assign a responsible person in charge of the quality assurance duties beforehand who meets the following requirements (hereinafter referred to as “quality assurance manager” in this Chapter).

- (1) To be the person who has competence for conducting the quality assurance duties properly and efficiently, and
- (2) Not to be the person who belongs to the department engaged in the sales of the drugs, etc. nor who could hinder the proper and efficient conduct of the quality

assurance duties.

(Documents and Duties, etc. concerned with Quality Assurance Duty Procedure)

Article 18 The marketing authorisation holder of quasi-drugs, etc. shall establish documents for the following procedures for proper and efficient conduct of the quality assurance duties (hereinafter referred to as “quality assurance duty procedure documents” in this Chapter).

- (1) The procedure for establishing records concerned with market release,
 - (2) The procedure for ensuring the proper manufacturing control and quality control,
 - (3) The procedure for handling the information on quality, etc. and quality defects, etc.,
 - (4) The procedure for handling recall,
 - (5) The procedure for controlling the documents and records, and
 - (6) Other necessary procedures for proper and efficient conduct of the quality assurance duties.
2. The marketing authorisation holder of quasi-drugs, etc. shall conduct the following duties in accordance with the quality assurance duty procedure documents.
- (1) To establish records concerned with market release,
 - (2) To verify that the quasi-drugs, etc. for marketing are manufactured properly and efficiently by the manufacturers, etc., and to establish records of the verification,
 - (3) To evaluate the effects of, and to investigate the cause of the matters concerned with the quality information on the human health in case where the marketing authorisation holder has received the information on the quality, etc. concerned with the products, and to make necessary improvements in case where they are necessary and to establish records thereof,
 - (4) To provide promptly in writing the safety control manager specified in Paragraph 2 of Article 13 applied *mutatis mutandis* under Article 14 of Standards for Post-marketing Safety Management (hereinafter referred to as “safety control manager”) with the information specified in preceding Item (3) which is concerned with the measures to ensure safety,
 - (5) To promptly take necessary actions including recall in case where the marketing authorisation holder has identified quality defects or their possibility of the quasi-drugs, etc. for marketing, and to establish records thereof, and
 - (6) To conduct other necessary duties concerned with the quality assurance duties.
3. The marketing authorisation holder of quasi-drugs, etc. shall place the quality assurance duty procedure documents in the office where the general marketing manager conducts

his/her duties, and also place copies thereof in other offices where the quality assurance duties are conducted.

(Provision to be Applied *Mutatis Mutandis*)

Article 19 The provisions of Article 3, Paragraph 1 of Article 4, Article 8 and Article 16 shall be applied *mutatis mutandis* to the standards for quality assurance for quasi-drugs, etc. In this case, “the quality assurance manager specified in Paragraph 3 of next Article” in Item (1) of Article 3 shall read “the quality assurance manager”, “, in addition to those specified in Item (2) of Paragraph 2 of Article 11, based on the reports from the quality assurance manager specified in preceding Item (1)” in Item (2) of Article 3 shall read “based on the reports from the quality assurance manager”, “the quality assurance department specified in Paragraph 2 of next Article” in same Item shall read “the quality assurance manager”, “other departments or responsible persons” in same Item shall read “the responsible persons in charge of the duties”, “the quality assurance manager specified in preceding Item (1)” in Item (3) of Article 3 shall read “the quality assurance manager”, “the quality assurance department specified in preceding Item (2)” in Item (4) of Article 3 shall read “the quality assurance manager”, “the safety control management department specified in Paragraph 1 of Article 4 of the Ministerial Ordinance on Standards for Post-marketing Safety Management for Drugs, Quasi-drugs, Cosmetics and Medical Devices (MHLW Ministerial Ordinance No. 135, 2004, and hereinafter referred to as “Standards for Post-marketing Safety Management”) or, for the marketing authorisation holder of drugs other than those specified in Paragraph 1 of Article 49 of Law, with the safety control manager specified in Paragraph 2 of Article 13 of Standards for Post-marketing Safety Management (hereinafter referred to as “safety control management department” in this Chapter)” in same Item shall read “the safety control manager”, “other departments concerned with” in same Item shall read “the responsible persons in charge of the duties concerned”, “the quality assurance duty procedure documents, etc.” in Article 8 shall read “the quality assurance duty procedure documents”, “the quality assurance duties to the general marketing manager, in addition to those reported to him/her in accordance with the provisions of Item (3)c. of Paragraph 5 of Article 9, Item (3) of Paragraph 2 of Article 10, Item (4) of Paragraph 1 of Article 11, Items (1) and (5) of Paragraph 2 of Article 11, Item (2) of Article 12, and Paragraph 2 of Article 13” in same Article shall read “the quality assurance duties to the general marketing manager”, “, distributors, pharmacy proprietors, hospital proprietors, clinic proprietors and other” in same Article shall read “other”, “the quality assurance duty procedure documents, etc.” in Article 16 shall read “the quality assurance duty procedure documents”, and “the following period” in Item (3) of same Article shall read “5 years”.

(Exceptions to Standards for Quality Assurance for Quasi-drugs Designated by Minister of Health, Labour and Welfare)

Article 20 The provision of preceding Chapter 2 shall be applied to the marketing of the quasi-drugs designated by the Minister of Health, Labour and Welfare as those that require special attention to their manufacturing control or quality control in accordance with the provision of Paragraph 2 of Article 20 of Enforcement Order of Pharmaceutical Affairs Law (Cabinet Order No. 11, 1961), notwithstanding the provisions of preceding three Articles 17, 18 and 19.

Chapter 4 Standards for Quality Assurance for Medical Devices

(Handling of Notifications on Repairs)

Article 21 The marketing authorisation holder of medical devices shall, in case where he/she has received the notification specified in Paragraph 6 of Article 191 of the Enforcement Regulations of the Pharmaceutical Affairs Law (including the case where it is applied *mutatis mutandis* under Article 192), have the person designated beforehand in the quality assurance department specified in Paragraph 2 of Article 4 applied *mutatis mutandis* under Article 25 give in writing the repairers the instructions for the proper repairing procedures and other matters necessary for maintaining the quality, efficacy and safety of the medical devices, in accordance with the quality standard code specified in Article 5 applied *mutatis mutandis* under Article 25 and the quality assurance duty procedure documents specified in Paragraph 1 of Article 6 applied *mutatis mutandis* under Article 25 (hereinafter referred to as “quality assurance duty procedure documents, etc.” in this Chapter).

(Quality Assurance by Distributors or Leasers)

Article 22 The marketing authorisation holder of medical devices, in accordance with the quality assurance duty procedure documents, etc., shall give in writing the distributors and leasers (hereinafter referred to as the “distributors, etc.” in this Chapter) the instructions for the procedures established beforehand for ensuring the quality of the medical devices for marketing in their offices.

(Handling of Notifications Concerned with Distributing or Leasing Used Devices)

Article 23 The marketing authorisation holder of medical devices shall, in case where he/she has received the notification specified in Paragraph 1 of Article 170 (including the case where it is applied *mutatis mutandis* under Paragraphs 2 and 3 of Article 178) of the Enforcement Regulations of the Pharmaceutical Affairs Law, have the person designated beforehand in the quality assurance department specified in Paragraph 2 of Article 4 applied *mutatis mutandis* under Article 25, in accordance with the quality assurance duty procedure documents, etc., give in writing the distributors, etc. the instructions for the actions necessary for maintaining the quality, efficacy and safety of the medical devices.

(Control of Documents and Records Concerned with Medical Devices)

Article 24 The marketing authorisation holder of medical devices shall maintain the documents and records concerned with the specially designated maintenance-control-required medical devices, or the installation-control-required medical devices (excluding the specified biological-origin products and the human-blood-origin products) for 15 years (5 years for those concerned with the training) from the date of the establishment (from the date when they fell into disuse for the quality assurance duty procedure documents, etc.), notwithstanding the provision of Item (3) of Article 16 applied *mutatis mutandis* under next Article.

(Provisions to be Applied *Mutatis Mutandis*)

Article 25 The provisions of Article 3 to Article 16 (excluding Item (3)c. of Paragraph 1 of Article 15) shall be applied *mutatis mutandis* to the standards for quality assurance for medical devices. In this case, “drugs other than those specified in Paragraph 1 of Article 49 of Law” in Item (4) of Article 3 shall read “the controlled medical devices and the general medical devices”, and “pharmacy proprietors” in Article 8 shall read “repairers, leasers”.

2. The quality assurance duty procedure document specified in Paragraph 1 of Article 6 applied *mutatis mutandis* under preceding Paragraph 1, shall describe the following matters.
- (1) The procedure for handling the notifications from the repairers,
 - (2) The procedure for ensuring the quality of the medical devices by the distributors and leasers, and
 - (3) The procedure for handling the notifications from the distributors or leasers of the used medical devices.

Supplementary Provision

This Ministerial Ordinance shall come into effect on 1 April 2005.



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