Article Content

Title：	Regulations of Medicament Manufacturer Inspection CH
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Category：	Ministry of Health and Welfare（衛生福利部）

Article 1 This set of regulations is formulated in accordance with regulations of Paragraph 3, Article 71 of the Pharmaceutical Affairs Act.

Article 2 Medicament manufacturers that shall be inspected in accordance with this set of regulations are as follows:
(1) Firms in the manufacturing, processing of pharmaceutical products;
(2) Firms in the manufacturing, assembling of medical devices;
(3) Other firms related to the manufacturing, processing or assembling of medicaments, including firms that are approved by the central competent health authority to manufacture medicaments for development, firms that produce drug labeling, and firms related to the packaging of medicaments.

Article 3 Inspections of medicament manufacturers shall be categorized as following:
(1) Inspections of the new establishment, relocation, expansion, resumption of operations, or addition of new active pharmaceutical ingredients, dosage forms, processes (packaging and labeling), products;
(2) Inspections of the follow-up management of medicament manufacturers;
(3) Regional routine inspections;
(4) Other types of inspections.
Domestic medicament manufacturers mentioned in Subparagraph 1 of the preceding Paragraph, their hardware facilities and sanitary conditions must comply with regulations of Part 2 of the Standards for Medicament Factory Establishments and the Factory Management Guidance Act, and shall be subject to inspection by the competent industry authorities and municipal or county (city) competent health authorities; their software facilities and sanitary conditions must comply with regulations of the Pharmaceutical Good Manufacturing Practice, and shall be subject to inspection by the central competent health authority in accordance with regulations of Article 4 or Article 6.
Foreign medicament manufacturers mentioned in Subparagraph 1 of Paragraph 1 must comply with regulations of the Pharmaceutical

Good Manufacturing Practice, and shall be subject to inspection by the central competent health authority in accordance with regulations of Article 5 or Article 7.
For inspections mentioned in Subparagraph 2 of Paragraph 1, domestic medicament manufacturers shall be inspected in accordance with regulations of Article 8, and foreign medicament manufacturers shall be inspected in accordance with regulations of Article 9.
Firms approved by the central competent health authority to manufacture medicaments for development, if applications for marketing of their products are not made, regulations of the three preceding Paragraphs may not apply. However, their medicaments for clinical trials shall comply with regulations of the Pharmaceutical Good Manufacturing Practice, and shall be subject to inspection by the competent health authorities.
Inspections mentioned in Subparagraph 3 of Paragraph 1 shall be conducted in accordance with regulations of Article 11.
Inspections mentioned in Subparagraph 4 of Paragraph 1 shall be conducted in accordance with regulations of Article 12.

Article 4 Domestic pharmaceutical manufacturers of the new establishment, relocation, expansion, resumption of operations, or addition of new active pharmaceutical ingredients, dosage forms, processes (packaging and labeling), shall apply for inspection by submitting a fee, along with a completed GMP Accreditation Application Form and the following documents to the central competent health authority:
(1) A certificate proving that hardware facilities have passed inspection, or a certificate of factory registration;
(2) A completed checklist of general information of a pharmaceutical manufacturer, along with Site Master File (hereafter shortened to “SMF”) containing the items detailed in the checklist.
For the inspection referred to in the preceding Paragraph, the central competent health authority may, jointly with the municipal or county (city) competent health authorities, conduct the on-site inspection.

Article 5 For foreign manufacturers of imported pharmaceuticals mentioned in Subparagraph 1, Paragraph 1 of Article 3, the Taiwan agents (pharmaceutical companies) shall apply for inspection by submitting a fee, along with completed application materials and a Plant Master File (hereafter shortened to “PMF”) containing the items detailed in the application materials to the central competent health authority. However, for manufacturers of countries approved by the central competent health authority, the PMF may be replaced by the SMF and an inspection report from said country’s competent health authority.

The PMF and SMF referred to in the preceding Paragraph shall be certified by the highest competent health authority or chamber of commerce in the country of origin. However, if documents from the highest competent health authority in the country of origin proving that the manufacturer is in compliance with local pharmaceutical GMP standards, or the original copy of a manufacturing and sales approval certificate clearly stating that said manufacturer is in compliance with local pharmaceutical GMP standards are submitted, the above certification is not required. If the country of origin is Germany, the documents may be issued by the competent health authority of a German state government, certification by the German federal government is not required.
If inspection of foreign factory is required as part of the inspection mentioned in Paragraph 1, the applicant shall submit a fee to the central competent health authority, and coordinate with the foreign manufacturer in preparing the information required for the inspection process.

Article 6 Domestic medical device manufacturers of the new establishment, relocation, expansion, resumption of operations, or addition of medical device products, shall apply for inspection by submitting a fee, along with two completed application forms and the following documents to the central competent health authority:
(1) Quality manual;
(2) A certificate of factory registration;
(3) Permit license of pharmaceutical manufacturer.

Article 7 For foreign manufacturers of imported medical devices mentioned in Subparagraph 1, Paragraph 1 of Article 3, the Taiwan agents (pharmaceutical companies) shall apply for inspection by submitting a fee, along with two completed application forms and the following documents to the central competent health authority:
(1) Documents of the quality system of the foreign manufacturer of imported medical device;
(2) Certificate of compliance equivalent to medical device GMP certification;
(3) Plant layout diagram, as well as information on product production areas, major equipment, and manufacturing processes from the foreign manufacturer of the imported medical device; where necessary, information on production personnel and transportation channels may be required for the application process.
For the documents of quality system mentioned in Subparagraph 1 of the preceding Paragraph, the applicant may first submit a quality manual, documents of relevant procedures, and document

master list. When necessary, the applicant must submit additional quality system documents or information as per the instructions of the central competent health authority.
If the country of origin of the manufacture is the United States, the applicant may submit a manufacturing and sales approval certificate from the highest competent health authority of the U.S., clearly stating that the manufacturer is in compliance with the US Pharmaceutical Current Good Manufacturing Practices (e.g. ISO 13485 Certificate), in place of the documents mentioned in Subparagraph 2 of Paragraph 1.
If the country of origin of the manufacture is the United States, Puerto Rico or Guam, as long as the Taiwan-U.S. medical device technical cooperation and document exchange program is valid, the applicant may submit an audit report and manufacturing and sales approval certificates issued by the highest competent health authority of the U.S., along with a certificate of compliance equivalent to a medical device GMP certificate (e.g. ISO 13485 Certificate), in place of the documents mentioned in Subparagraph 1 through Subparagraph 3 of Paragraph 1.
If the country of origin of the manufacture is an EU member state, Switzerland, or Liechtenstein, as long as the Taiwan-EU, Taiwan-Swiss, or Taiwan-Liechtenstein medical device technical cooperation and document exchange program is valid, the applicant may submit an audit report issued by an EU medical device notified body that has received cooperation approval documents from the central competent health authority and is party to the audit report exchange technical cooperation agreement with medical device GMP notified bodies designated by the central competent health authority, along with manufacturing and sales approval certificates from the highest competent health authority in said country, and a certificate of compliance equivalent to a medical device GMP certificate (e.g. ISO 13485 Certificate) from the relevant medical device notified body that has received cooperation approval documents, in place of the documents mentioned in Subparagraph 1 through Subparagraph 3 of Paragraph 1.
If inspection of the foreign factory is required as part of the inspection mentioned in Paragraph 1, the applicant shall submit a fee, along with the foreign manufacturer’s quality manual, to the central competent health authority, and coordinate with the foreign manufacturer in preparing the information required for the inspection process.

Article 7-1 If the documents for the application of medical device GMP compliance are insufficient, the applicant should submit the required supplementary documents in two months. If the

supplementary documents can not be prepared accordingly and timely, the applicant can apply for an extension of one additional month in time. The extension is granted for once only. If the supplementary documents can not be submit in time (with or without extension), the central competent health authority will make decision by the existing documents.

Article 8 The inspections of domestic pharmaceutical manufacturers mentioned in Subparagraph 2, Paragraph 1 of Article 3 shall be conducted every two years and may extend one to two years depending on the types of dosage forms manufactured, process activities and inspection history. Domestic medical device manufacturers shall be inspected every three years.
Manufacturers must apply for inspections mentioned in the preceding Paragraph six months prior to the expiration of their medicament manufacturing license.
When the central competent health authority deems it necessary, or finds that a medicament poses a major hazard, additional for-cause inspections may be conducted without prior notification of the inspected party.
Of the inspections mentioned in Paragraph 1 and 3, the central competent health authority inspects the current status of pharmaceutical GMP or medical device GMP implementation by manufacturers; it may notify the municipal or county (city) competent health authorities and the competent industry authorities to participate in the inspection. Manufacturers shall cooperate with the inspection in accordance with regulations of Article 4 or Article 6.

Article 9 The follow-up inspections of foreign pharmaceutical manufacturers of imported drugs shall be conducted every two years and may extend one to two years depending on the management system and standards for pharmaceutical manufacturing in country of origin; in addition to document review, on-site inspections shall be conducted depending on types of dosage forms of imported products, process activities, inspection history and the management system and standards for pharmaceutical manufacturing in country of origin. The foreign medical device manufacturers of imported medical device shall be inspected every three years.
Manufacturers must apply for inspections mentioned in the preceding Paragraph six months prior to the expiration of their approval documents.
When the central competent health authority deems it necessary, or finds that a medicament poses a major hazard, additional for-cause inspections may be conducted.
Of the inspections mentioned in Paragraph 1 and 3, the central competent health authority inspects the current status of

pharmaceutical GMP or medical device GMP implementation by manufacturers. Manufacturers shall cooperate with the inspection in accordance with regulations of Article 5 or Article 7.

Article 10 Domestic medicament manufacturers in compliance with regulations of Article 4,Article 6, and Article 8 will be issued with medicament manufacturing licenses by the central health authority.
Foreign medicament manufacturers in compliance with regulations of Article 5,Article 7, and Article 9 will be issued with approval documents by the central health authority.

Article 11 Inspections mentioned in Subparagraph 3, Paragraph 1 of Article 3, of local medicament manufacturers shall be conducted by the municipal or county (city) competent health authorities jointly with the competent industry authorities; the frequency and focus of these inspections shall be as follows:
(1) Once a year;
(4) Inspections shall focus on the medicament manufacturer’s facilities, operational procedures of production, processing and assembly, quality control, finished products, semi-finished products, raw materials, accessory containers, packaging, labels, instructions, and factory or site safety, machinery layout and operating efficiency.

Article 12 Other inspections shall be conducted by the competent health authorities and the competent industry authorities in accordance with relevant regulations, or as needed, based on jurisdiction.

Article 13 When conducting the various inspections, the competent authority may, as needed, invite relevant organizations or experts to participate in the inspection process.

Article 14 When conducting inspections, the inspector shall present proof of identity (i.e. Inspector Badge). During inspections, said personnel may ask for and make copies of relevant documents; when necessary, they may obtain samples, take photographs and make audio recordings for evidence.
If the inspected party refuses, evades or interferes without reasons, the inspection may directly be determined non-compliance.

Article 15 For deficiencies found on inspections, medicament manufacturers shall make necessary corrective actions in accordance with inspection reports or other relevant documents of the inspecting authority by the required date, and submit a corrective action report.
Where the inspected party is found to be in non-compliance, has not made necessary corrective actions by the required date, or

submits a corrective action report, the inspecting authority may discipline said party in accordance with relevant regulations.

Article 15-1 Pharmaceutical companies that apply for manufacturing medical devices shall comply with medical device GMP regulations. If the inspection is determined non-compliance, pharmaceutical companies may apply for re-inspection in 2 month from the date of determination. The re-inspection is for once only.

Article 16 Application forms stipulated in this set of Regulations shall be determined by the central competent health authority.
The inspected party shall prepare the information required for the inspection in accordance with the items stipulated in said application forms. In filling out application forms and providing accompanying information, only traditional Chinese characters and English shall be used; where text that is not in traditional Chinese or English, a traditional Chinese version or English translation must be provided.

Article 17 This set of regulations shall be implemented on the date of announcement.
