Article Content

Title：	Regulations for Medicament Recall CH
Announced Date：	2015-08-05
Category：	Ministry of Health and Welfare（衛生福利部）

Article 1 These regulations are promulgated pursuant to Paragraph 3 of Article 80 of the Pharmaceutical Affairs Act (the Act)

Article 2 Operational procedure of medicament recalls shall be classified into 3 classes according to the risks to health as following.
1.Class I:
(1).Drugs which have been deemed counterfeit or prohibited in accordance with Subparagraph 2 of Paragraph 1 of Article 80 of the Act, and medical devices which have been manufactured or imported without approval in accordance with Subparagraph 3 of Paragraph 1 of Article 80 of the Act.
(2).Medicament which are to be damaging the life, body or health of users in accordance with Subparagraph 4 of Paragraph 1 of Article 80 of the Act.
(3).Medicament in accordance with Subparagraph 1, misbranded drugs in accordance with Subparagraph 2, defected medical devices in accordance with Subparagraph 3 and medicament in accordance with Subparagraph 4 of Paragraph 1 of Article 80 of the Act, which are to be likely to cause material damage to the life, body or health and have been deemed by central health competent authority.
2.Class II: Medicament in accordance with Subparagraph 1, misbranded drugs in accordance with Subparagraph 2, medical devices which have been deemed defective in accordance with Subparagraph 3 and medicament in accordance with Subparagraph 4 of Paragraph 1 of Article 80 of the Act which are other than Item 2 and Item 3 in the preceding Subparagraph.
3.Class III: Medicament which are according with Subparagraph 5 and 6 of Paragraph 1 of Article 80 of the Act.

Article 3 Manufacturers or importers of medicament shall finish their recall procedure within the time period as following:
1.Class I: Within one month since the day following publicly announcement or the date of recall has been deemed duly.
2.Class II: within two months since the day following publicly announcement or the date of recall has been deemed duly.
3.Class III: within six months since the day following the expiration date of the medicament permit license or approval to

change the package, label, or use instruction.
Whenever products shall be recalled which are drugs have been deemed counterfeit, prohibit, misbranded and medical devices have been deemed defected and manufactured or imported without approval, municipal or city (county) competent health authority shall be processed in accordance with Article 78 and 79 of the Act as the priority.

Article 4 Whom shall be processed the recall with the manufacturers and importers as following:
1.Class I and Class II: Medical care institutions, pharmacies and pharmaceutical firms.
2.Class III: Pharmacies and pharmaceutical firms.

Article 5 A medicament recalled according to Article 3 along with those products in the stock shall be processed as following:
1.Class I and Class II:
(1).Drugs which have been deemed counterfeit or prohibited in accordance with Subparagraph 2 of Paragraph 1 of Article 80 of the Act shall be confiscated and destroyed.
(2).Whenever medicament is in accordance with Subparagraph 1 and 4, misbranded drugs in accordance with Subparagraph 2, medical devices in accordance with Subparagraph 3 of Paragraph 1 of Article 80 are domestic products and considered, after testing, to be still useful through re-modification, the municipal or city (county) competent health authority shall assign an official to supervise the original manufacturer to re-modify within a time limit. Those can not be re-modified or have not been re-modified after expiry of the given time limit shall be confiscated and destroyed. If the use seized are of approved imports, they shall be placed in confinement immediately and the municipal or county (city) competent health authority shall direct the original importer to return such products to the foreign supplier(s) within a time limit. Those have not been returned beyond the given time limit shall be confiscated and destroyed.
2.Class III: Products can be sold after to be examined by and receive the seal of the municipal or city (county) competent health authority.

Article 6 Whenever the municipal or county (city) competence health authority orders a manufacturer or an importer in its jurisdiction to launch a Class I or II medicament recall, it shall inform central and other municipal or county (city) competence health authority.

Article 7 The competence health authority in each level may disclose the medicament’s name, specification, license permit number, batch

number or serial number for identification and coding of the medicament, the name and address of the manufacturer or importer, and the reason of the recall on the website of the authority or public media.

Article 8 Medicament manufacturers or importers shall establish a complete distribution record, and urge their dealers to keep the related distribution record. Both records shall include the product name, content, dosage, batch number, name and address of the recipient, shipping date and quantity of distributions.

Article 9 Medicament manufacturers or importers shall set up the procedure of medicament recall operation, which content shall include the organization of the recall operation, designated personnel and their mission, the proposal of recall operation, notify of the recall messages, recall the products from the market and in the stock, and produce the report with documented operation procedures and results.

Article 10 Medicament manufacturers or importers in accordance with the recall procedure in Class I and Class II, shall notify their direct distributors in accordance with Subparagraph 1 of Article 4 of this regulation within 24 hours since the day following notify or the date of recall has been deemed duly.

The content of the preceding paragraph shall include the following:

1.Name, address, and telephone number of the medicament manufacturers or importer.

2.Name, specification, and permit license number of the medicament.

3.The batch number or serial number for identification and coding of the medicament.

4.The reason of recall and the damage it may cause.

5.Recall methods, time and location for recall delivery.

6.The requirements shall be complied by the direct distributors

Medicament manufacturers or importers shall keep the written record of the receiving personnel from the direct distributors, the time and the methods for notifications, and the responsible person for the notifications.

The record required by preceding paragraph shall be kept at least 5 years.

Article 11 Medicament manufacturers or importers in accordance with the recall procedure in Class III, shall notify their direct distributors in accordance with Subparagraph 2 of Article 4 of this regulation.

Paragraph 2 to Paragraph 4 in the preceding article shall apply mutatis mutandis in this Article.

Article 12 Medicament manufacturers or importers in accordance with the recall procedure in Class I and Class II, shall produce a proposal of recall operation and submit to the municipal or county(city) competent health authority and central competent health authority within 3 days since the day notify or the date of recall has been deemed duly, and the competent health authority may request for correction.

The proposal of recall operation in the preceding paragraph shall include the following:

1.Name, address, and telephone number of the medicament manufacturer or importer.

2.Name, specification, and permit license number of the medicament.

3.The batch number or serial number for identification and coding of the medicament.

4.The total quantity, sales quantity, and inventory quantity of the medicament manufactured domestically or imported.

5.Name, address, and their individual sales quantity of the medical care institution, pharmacies, and pharmaceutical firms.

6.Name of the export country, name, address and their individual sales quantity of the target distributors from the domestic manufacturer medicament exporter.

7.The reason of recall and the damage it may cause.

8.The scheduled date for recall completion.

9.The methods, contents, and other related procedures taking indicate in the notification to the medical care institutions, pharmacies, and pharmaceutical firms of the direct distributors.

Article 13 Medicament manufacturers or importers in accordance with the recall procedure in Class III, shall produce a proposal of recall operation and retain for future inspection. The content shall include the following:

1.Name, address, and telephone number of the medicament manufacturer or importer.

2.Name, specification, and permit license number of the medicament.

3.The batch number or serial number for identification and coding of the medicament.

4.The total quantity, sales quantity, and inventory quantity of the medicament manufactured domestically or imported.

5.Name, address, and their individual sales quantity of the domestic direct distributors of the pharmacies and pharmaceutical firms.

6.The reason of recall.

7.The scheduled date for recall completion.

8.The methods, contents, and other related procedures taking

indicate in the notification to the pharmacies and pharmaceutical firms of the direct distributors.

Article 14 The municipal or county(city) competent health authority shall supervises the medical care institutions, pharmacies, and pharmaceutical firms in its jurisdiction to process the recall procedures in accordance with Article 80 of the Act.
The municipal or county(city) competent health authority shall initiate an inspection or conduct an inspection in response to the notification of Class I recall procedure from other health competent authority within 10 days, to the medical institutions, pharmacies, and pharmaceutical firms in its jurisdiction. The recall medicament shall be off-the-shelf and other recall procedure shall be acknowledged.

Article 15 Medicament manufacturers or importers shall give identification and labels both on the recall medicament and inventory and store them separately.

Article 16 Medicament manufacturers or importers in accordance with the recall medicament in Class I and Class II, shall produce the report with documented operation procedures and results and submit to the municipal or county(city) competent health authority and central competent health authority within 3 days after the day of recall completion. The competent authority may request for supplements or correction.
The report with documented operation procedures and results in the preceding paragraph shall include the following contents:
1.Name, address, and telephone number of the medicament manufacturer or importer
2.Name, specification, and permit license number of the medicament.
3.The batch number or serial number for identification and coding of the medicament.
4.The total quantity, sales quantity, and inventory quantity of the medicament manufactured domestically or imported; they shall all be recorded separately into recalled and not recalled items and quantity.
5.The recall items and quantity lists from each recall targets.
6.Recall completion date, storage location for recalled products, and the follow-up handling method and date.
7.Follow-up corrective and preventive actions for the reason to recall.

Article 17 Medicament manufacturers or importers in accordance with the examination and seal for the recall medicament in Class III, shall prepare and fill out a seal application and submit to the municipal or county(city) competent health authority.

The seal application shall include the following:
1.Name, address, and telephone number of the medicament manufacturer or importer.
2.Name, specification, and permit license number of the medicament.
3.The batch number or serial number for identification and coding of the medicament.
4.The total quantity, sales quantity, and inventory quantity of the medicament manufactured domestically or imported.
5.The reason and accordance to apply for examination and seal.

Article 18 The municipal or county(city) competent health authority shall conduct an inspection on the follow-up handling method and scheduled date of the recall medicament in Class I and Class II, by their manufacturers or importers in its jurisdiction and report the result of inspection to central competent health authority for future reference.

Article 19 These regulations shall be effective as the date of promulgation.
