Ch6
Special planning

CHAPTER

06

Optimize the Hygiene and Safety Management of Cosmetics

- Reinforce drug management during the pandemic control period
- Implementation of relief subsidy measures for pharmaceutical companies
- Accelerated the review process of COVID-19 drugs and assisted the research and development of vaccines

Management of Medical Devices Related to Pandemic Control

- Compiled license information for pandemic control medical devices, ensuring the supply
- Start green regulation channel to accelerate the approval and market launch of pandemic control medical devices
- Strengthen the quality and safety management of medical masks
- Establish a sound environment for the development of the pandemic control medical device industry

Name-Based Mask Distribution System 1.0

- Rolling adjustment of the distributed quantity to improve the convenience of people's purchase
- A total of 84,412 cases of the Name-Based Mask Distribution System 1.0 have been handled by the 1919 food safety consultation hotline
- A total amount of NT$178,540,000 was distributed to reward pharmacies for cooperating with the government in handling the Name-Based Mask Distribution System
- The Masks Distribution and Sale Big Data Analysis System for closing entries, with a total amount of NT$5,170,923,214
- Established the notification and handling of defective mask
- Produced a total of 386 epidemic control messages, of which 164 promoted the Name-Based Mask Distribution System

Ch6 Special planning

2020 was the year for the nation to unite as one to fight against severe acute respiratory infection (hereinafter referred to as COVID-19) pandemic. Under the leadership of the "Severe Acute Respiratory Infection Central Epidemic Command Center" (hereinafter referred to as the Command Center), various agencies collaborated together to organize various pandemic control materials and supplies in advance. The Agency was responsible for managing medical products, successfully providing supplies to the efforts of pandemic control.

In order to illustrate the results of the Agency's efforts in pandemic control, this chapter fully presents the preparation of pandemic control drugs, vaccines, and medical devices, as well as the distribution plan of real-name registration system 1.0 for masks, including coordinating supply and demand, accelerating review and proactive counseling, and facilitating promotion. The joint efforts of the public and private sectors, laid the foundation for pandemic control.

Section 1

Drug Management and Pandemic Control Actions

Introduction of the Policy

In response to the outbreak of the COVID-19 pandemic, TFDA has prepared a number of contingency measures, such as proactive inventory of drugs, formulation of relevant management principles, priority review of API related applications, and accelerated review of pandemic control drugs, in order to prevent the disorder of domestic drug supply and protect the rights and interests of citizens using drugs and receiving treatment. There are relevant counseling measures to continuously track the status of research and development of drugs and vaccines at home and abroad, and help accelerate the R&D and market launch of therapeutic drugs and vaccines.

Implementation Strategy

I. Reinforced drug management during the pandemic control period

(I) Since February 2020, TFDA has prioritized accelerating the review of changes in the source of active pharmaceutical ingredients, importing of raw materials for self-use, etc., and at the same time, we also encouraged the industry to look for alternative sources of active pharmaceutical ingredients in

advance. In terms of alcohol supply, in addition to accelerating the reviewing process to assist medicinal alcohol manufacturers for changing raw material supply, TFDA coordinated with two major state-owned enterprises to produce pandemic control alcohol to ensure the sufficient supply of alcohol.

(II) In order to prevent drug stockpiling and uneven supply caused by the pandemic, TFDA issued the "Management Principles for Drug Supply During the COVID-19 Pandemic" on March 17, 2020, requiring that pharmaceutical companies to distribute drugs to medical care institutions and pharmacies, and medical care institutions or pharmacies to purchase drugs, which is based on the monthly sale in the past year. If the quantity exceeds the average monthly sale in the past year by more than 10%, reasons and supporting documents must be submitted to TFDA for approval.

(III)TFDA announced and implemented the "*Guidelines for the Management of Uneven Distribution of Medicines During the COVID-19 Pandemic*" on April 13, 2020, to effectively handle issues such as excessive order of medical care institutions and an increase of drug inventory caused by the decrease in outpatient visits. Also, a dedicated reporting mailbox (tfdawatch@fda.gov.tw) was established for reporting drug stockpiling, uneven distribution, etc. to facilitate the follow-up investigations.

II. Formulated relief measures for drug sellers with operational difficulties

Since the pandemic affects the drug supply chain, it also increases the cost of APIs and preparations, which also decreases the willingness or capability of drug manufacturers to manufacture or import drugs. Under this circumstance, TFDA has proposed relief subsidies for drug companies in the Compensation and Relief Measures for Medical Institutions, Enterprises, and Industries due to the Impact of Severe Pneumonia with Novel Pathogens, which was announced and implemented on March 12, 2020. Pharmaceutical companies that meet the requirements for operational difficulties can receive subsidies for manufacturing or importing expense of drugs to relieve the pressure of competition of raw materials and supplies. Apart from that, it also stabilizes the drug supply chain and maintains the operation of the medical care system. At the same time, relevant information is also integrated into the webpage of the Ministry of Health and Welfare and which is accessible for industry practitioners.

III. Accelerated the review process of COVID-19 drugs and assisted the research and development of vaccines

(I) In order to speed up the launching of domestic vaccine and maintain the quality and safety of the vaccine, TFDA and the Center for Drug Evaluation (CDE) became a project consulting and counseling team, which held weekly discussion meetings with manufacturers. The rolling review

practice not only shorten the timeline, but also provides the most immediate legal, technical consultation and guidance. On April 13, 2020, the CDE announced the "CDE can Help: COVID-19 Regulatory science counseling program", providing free consultation and counseling for the cases of COVID-19 drugs that have been selected.

(II) TFDA established the "Registration Platform for Intention to Participate in COVID-19 Vaccine Clinical Trials" on November 11, 2020, for those people who are willing to participate in COVID-19 vaccine clinical trials to register online, assisting accelerate the clinical trials in domestic vaccine.

Achievements and Benefits

I. Reinforced drug management during the pandemic control period

In 2020, there were a total of 436 applications for the new APIs source of medicinal products, and nearly 2,700 applications of importing raw materials for domestic pharmaceutical use. TFDA accelerated the review of the sources of new APIs and shortened the announcement period by half to prevent shortages. By strengthening the supply mechanism of drug, the stable supply of drugs was ensured during the pandemic. TFDA also coordinated with the distribution of alcohol supply to ensure that medical institutions had sufficient usage, so as improve the convenient access to the public.

II. Implementation of relief subsidy measures for pharmaceutical companies

Since the implementation of relief subsidy measures for pharmaceutical companies on March 12, 2020, a total of 11 applications from 8 western medicine sellers have applied as of the end of 2020. 6 items of 4 applications for relief subsidies have been approved, with a total of NT$1,039,375.

III. Accelerated the review process of COVID-19 drugs and assisted the research and development of vaccines

(I) As of the end of 2020, 21 applications have been included in project consultation and counseling, which includes 11 for vaccines, 7 for medicines, and 3 for cell products. Three domestic COVID-19 vaccines entered phase 1 clinical trials, one of which entered phase 2 of clinical trials at the end of the same year. A special approval has been granted to the import license of a COVID-19 drug, Remdesivir. TFDA will continue to provide consultation with the COVID-19 drugs and vaccines under the development to help them launch in the market as quickly as possible.

(II) From November 11 to November 30, 2020, the total number of registrations to the "Registration Platform for Intention to Participate in COVID-19 Vaccine Clinical Trials" reached 21,190. The medical institutions which conducts clinical trials can apply for access to the data on the platform to contact potential participants in clinical trials of the domestic vaccines.

Section 2

Management of Medical Devices Related to Pandemic Control

Introduction of the Policy

At the start of the COVID-19 pandemic, countries fought for medical supplies, which resulted in an imbalance between supply and demand. Therefore, as the pandemic continues, it is vital for TFDA to have a clear picture of available medical devices in Taiwan; hence, we need to have information related to the supply and demand of such medical devices, which includes reporting, control and distribution of medical devices. At the same time, it is also important for us to speed up the market approval of medical devices related to the control of outbreaks, so as to ensure the quality, safety, and supply of medical devices required for the control of outbreaks.

Implementation Strategy

I. Took stock of permit license information of medical devices required for the control of outbreaks

In the early phase of the pandemic, TFDA quickly compiled the list of medical devices required licenses, for the control of outbreaks as well as information of their permit licenses. These medical devices include medical masks (N95, general medical and surgical mask), isolation gowns, full-body protective suits, forehead/ear thermometers, test kits, etc., for Taiwan Centers for Disease Control and the Ministry of Economic Affairs. TFDA also surveyed the manufacturing and import status of manufacturers, established points of contact with manufacturers, and held meetings to discuss alternative solutions.

II. Fast lane entry service to accelerate the market approval of medical devices required for prevention of outbreaks

In accordance with Subparagraph 2, Paragraph 1 of Article 48-2 of the "*Pharmaceutical Affairs Act*," the fast lane entry service will be made available to accelerate the application for manufacturing and importing as special cases. TFDA has actively provided firms with consultation services before they submit applications to manufacture medical devices that could help to control the outbreaks as special cases or apply for permits. A special hotline and a taskforce have been established to provide consultation regarding regulations. TFDA has also simplified the procedures by (1) simplifying the documents required for application for manufacturing as special cases; (2) simplifying the quality management system information submitted by the manufacturers; (3) announcing references used to review and test medical devices manufactured as special cases; (4) priority review conducted by assigned specialists. All these measures are taken to speed up the market approval of medical devices needed to control the outbreaks of COVID-19. In addition, to respond to the increasing demand for emergency COVID-19 testing, TFDA prepared SARS-CoV-2 standard and respiratory related virus panel for the qual-

ity control of molecular diagnostic reagents developed by the biotechnology industry, further promoting the domestic industry's efforts in pandemic control.

III. Strengthened quality management and safety management of medical masks

TFDA announced the amendments to the "*Regulations for the Inspection and Examination of Imported Medicaments*." Starting from July 7, 2020, medical masks will be included as one of the items to go through border inspection. At the same time, firms importing both non-medical masks and medical masks, or importing a large volume of non-medical masks will need to pass on-site inspections. Besides, TFDA also announced "*Particulars that Shall Be Indicated on the Labels of Flat Medical Masks*" requiring firms to ensure that flat medical masks should have "MD" and "Made in Taiwan" stamped on the masks starting from September 24, 2020.

IV. Established a sound environment for the development of the medical devices industry for control of outbreaks

To ensure that the capacity for research and development and manufacturing of medical devices for epidemic prevention accumulated during the COVID-19 pandemic can be maintained, TFDA provides special consultation for manufacturers who have obtained permission to manufacture medical devices as a special case to assist such firms to obtain licenses to manufacture medical devices. TFDA will continue to facilitate research and development in research institutions, academic units, as well as public and private sectors to promote the development of the industry.

Achievements and Benefits

I. Ensured the supply of medical devices for epidemic control

(I) As TFDA has sped up the issuance of market approval permits for medical devices needed for epidemic control, our statistics showed that from February 1 to December 31, 2020, 174 permits have been issued for medical masks, 36 permits for isolation gowns, 16 permits for forehead thermometers and 5 permits for respirators, so as to quickly meet the domestic demand for medical supplies to fight the pandemic.

(II) Meetings to discuss alternative solutions and other response measures to get a clear picture of the supply and demand of medical devices required for epidemic control which includes reporting, control and distribution of medical devices to ensure that the sufficient supply of medical devices in Taiwan.

II. Enhanced the R&D and manufacturing capacity of domestic medical devices

(I) With fast lane entry service initiated, from February 1 to December 31, 2020, TFDA has approved 76 applications for manufacturing of medical devices as special cases, including 25 applications for testing reagents, 1 application for

nasopharyngeal swab sampling robots, 1 application for respirators, 3 applications for forehead thermometers, 20 applications for isolation gowns, 17 applications for protective gowns, 7 applications for medical masks and 1 application for small electrocardiogram system. The approval encourages domestic firms to continue to conduct research and develop medical devices. We have also approved 111 applications for importing medical devices import as special cases for control of the outbreaks in Taiwan.

(II) TFDA prepared SARS-CoV-2 standard and respiratory related virus panel, and acquired the SNQ certification for medical peripheral products in 2020, demonstrating the inspection capabilities of Taiwan's national laboratories and the visibility and credibility of the preparation of biological standard products.

III. Strengthened the quality management and safety management of medical masks

To strengthen the quality management and safety management of medical masks, TFDA has announced the amendments of relevant regulations. Firms importing both non-medical masks and medical masks, or importing a large volume of non-medical masks will need to pass on-site inspections. These measures are taken to ensure the safety and effectiveness of imported medical masks from the source. Moreover, domestically manufactured flat medical masks are required to have "MD" and "Made in Taiwan" stamped on the masks to help the public identify authentic medical masks and prevent counterfeiting. For this measure, TFDA has conducted briefings, issued press releases, information for dummies and Q&A to accelerate the implementation of the policy.

IV. Established a sound environment for the development of the medical devices industry for control of outbreaks

TFDA worked closely with companies and research institutions who are interested to engage in R&D and production of medical devices in Taiwan to invest in the R&D and production of medical devices for control of outbreaks, turning the challenge posed by the pandemic into an opportunity for Taiwan to accumulate experience, transform and grow. The ultimate goals are for Taiwan's industry to acquire the ability to develop and prepare key raw materials; to establish a sound environment for the development of medical devices for epidemic control; and to strengthen the production capacity of Taiwan's biotechnology industry.

Section 3

Name-Based Mask Distribution System 1.0 and Related Measures

Introduction of the Policy

In the early phase of the COVID-19 epidemic, the government immediately implemented a Name-Based Mask

Distribution System 1.0 due to the incidents of rush buying and stockpiling masks. Additionally, due to the increasing demand for medicinal alcohol, the government also assisted the pharmacies with the distribution of medicinal alcohol. These measures ensured the fairness and accessibility of masks and alcohol purchases and enhanced the all citizens' epidemic prevention.

Implementation Strategy

I. Coordinated Name-Based Mask Distribution System and provide consulting services across various agencies.

In addition to regularly participating in cross-functional coordination meetings held by the CECC, TFDA actively held emergency meetings, inviting the associations of pharmacists and assistant pharmacists, the Chunghwa Post Co., Ltd., the Industrial Development Bureau of the Ministry of Economic Affairs, the National Health Insurance Administration of the Ministry of Health and Welfare (hereinafter referred to as the NHI Administration), and the Health Promotion Administration to discuss the response measures (Figure 6-1, 2) regarding the implementation of mask distribution and the encountered difficulties. TFDA then notified the NHI-contracted pharmacies (referred to as pharmacies) of the distribution and the Name-Based Mask Distribution System 1.0 and relevant tasks.

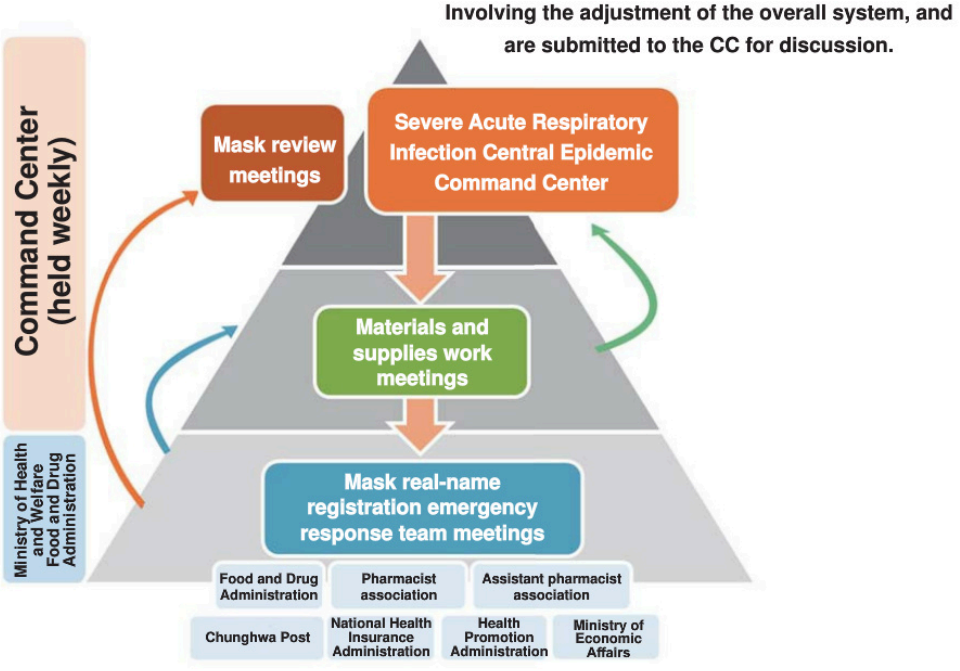

Figure6-1 Name-Based Mask Distribution System 1.0 and related measures

Figure6-2 The Name-Based Mask Distribution System 1.0 emergency response team meetings

TFDA's dedicated line (1919) for food safety consultation also started to support the epidemic control dedicated line (1922) under the instructions of the Executive Yuan to immediately respond to the issues raised by the public and distribution channels related to masks.

II. National mobilization and for the distribution of epidemic control materials and supplies

Under the Executive Yuan's leadership, about 6,000 pharmacies and 340 local health bureaus (including health service centers) participated in the Name-Based Mask Distribution System 1.0.

TFDA provided the distributed locations and quantities for the Name-Based Mask Distribution System 1.0 every day, and Chunghwa Post Co., Ltd. delivered the masks to all sales locations. Citizens purchased the masks with their national health insurance cards, and foreigners used their residence certificate or entry/exit permits to purchase through the NHI card system. TFDA controlled the number of distribution locations and collected the payments of masks through the Masks Distribution and Sale Big Data Analysis System interfacing with the through the Disease Prevention Mask Control System of the NHI.

Packaging envelopes for the Name-Based Mask Distribution System 1.0 were manufactured and provided to all sales locations so they can sell them to the public, and the subsidies on sales and packaging were given to the pharmacies to cover the manpower and working time needed.

In addition to handling the distribution of masks, TFDA helped the Associations of pharmacists and assistant pharmacists obtain 75% Ethyl Alcohol from by Taiwan Tobacco and Liquor Corporation, to the distribution to the pharmacies started from February 19, 2020.

III. Rolling adjustment of mask distribution and registration of quality issues

The distributed locations and quantities were adjusted in accordance with the CECC

and the daily sales and inventory of all sales locations. Considering the fairness of mask purchases, the initial implementation limited the purchase to 2 pieces in 7 days per person. Later on, due to the increase in mask production capacity, the allowance was raised to 9 pieces for adult masks or 10 pieces for children masks every 14 days starting April 9, 2020. A new packaging of 10 masks went into effect from December 31, 2020, and the adjustment measures are shown in Table 6-1.

Considering the quality of masks, TFDA compiled the defective notifications provided from all sales locations starting April, 2020. In order to prevent the mixing of non-medical masks with medical masks, TFDA required that starting September 24, 2020, double stamp of Medical Devices (MD) and Made in Taiwan must be marked on the masks.

IV. Multi-channel promotion

In response to the situations during the epidemic and adjustments of masks distribution, TFDA actively promoted epidemic control communication, including posters used at each sale points participated in the Name-Based Mask Distribution System 1.0, and policy descriptions and pandemic control-related materials used at various channels.

Table6-1 Name-Based Mask Distribution System 1.0 schedule

Date	Measures
February 6	Started implementing the Name-Based Mask Distribution System. Each person was allowed to buy 2 pieces of masks every 7 days, and each mask was charged NT$5. The traffic of buyers was split up based on the even/odd number of the last digit of the personal identification cards. A total of 6,280 NHI-certified pharmacies and 58 local health bureaus participated in the program.
February 16	The number of local health bureaus (including health service centers) that offered the Name-Based Mask Distribution System increased to 340.
February 27	Lifted the restrictions on the even/odd number of last digit of personal ID for children's masks.
March 5	The Name-Based Mask Distribution System for adults increased to 3 pieces for every 7 days, and 5 pieces for every 7 days for children.
April 9	The purchase cycle and quantity were adjusted to either 9 pieces for adults or 10 pieces for children over 14 days, and there were no age restrictions. The restrictions on the even/odd number of the last digit of personal IDs were also lifted.
April 19	Distribution of masks on Sunday was stopped. Pharmacies and local health bureaus could have the day off or voluntarily sell the masks in their inventory.
April 23	Restored the restrictions on the age limit for the purchase of children's masks. Available for purchase only with an NHI card whose cardholder is less than or equal to 16 years old.
June 1	1.Masks were available for all types of purchases. In addition to being available through the Name-Based Mask Distribution program, masks were available through other channels. 2.Local health bureaus would no longer be selling masks on Saturdays from that day.
September 24	Double stamp marks of MD and Made in Taiwan must be applied on the masks.
December 31	The number of pieces and the price of masks through the Name-Based Mask Distribution were changed to 10 pieces/pack for NT$40, available every 14 days.

Achievements and Benefits

I. Achievements of the Name-Based Mask Distribution System 1.0

(I) Rolling adjustment of the distributed quantity to improve the convenience of people's purchase

On the day before the Name-Based Mask Distribution System 1.0 was implemented, the distribution of 6,336 sales locations was completed. Each location was given 200 pieces of masks for adult and 50 pieces for children. The number of distributed pieces was gradually increased, as shown in Table 6-2.

As of December 31, 2020, a total of 1,115,210,000 pieces of adult masks and 187,400,000 pieces of children's masks were delivered, totaling approximately 1,302,610,000 pieces; 1,099,050,000 adult masks and 174,130,000 children's masks were sold, totaling approximately 1,273,180,000 pieces, representing a sales rate of 98%.

(II) Consultation services

As of the end of December 2020, a total of 84,412 cases of the Name-Based Mask Distribution System 1.0 have been handled by the 1919 food safety consultation hotline; a total of 21,630 mask-related cases were handled through the mailboxes of various director-generals and ministers, and other agencies.

(III) Rewards, subsidies and appreciation to professionals handling the epidemic control and pharmaceutical matters

In order to reward pharmacies for cooperating with the government in handling the Name-Based Mask Distribution System (Figure 6-3), those who cooperated and sold Name-Based masks for a total of 20 days (and more)

Table6-2 Mask distribution adjustment table for the Name-Based Mask Distribution System 1.0

Date	Adult masks		Children' masks		Total number of pieces (piece/day)
	Pieces (piece/day)	Person-time serviced (piece/person)	Pieces (piece/day)	Person-time serviced (piece/person)	
February 6 to February 19, 2020	200	100 (2 pieces/person)	50	25 (2 pieces/person)	250
February 20 to March 4, 2020	400	200 (2 pieces/person)	200	50 (4 pieces/person)	600
March 5 to April 8, 2020	600	200 (3 pieces/person)	200	40 (5 pieces/person)	800
April 9 to December 30, 2020	1,800	200 (9 pieces/person)	200	20 (10 pieces/person)	2,000
From December 31, 2020	2,000	200 (10 pieces/person)	200	20 (10 pieces/person)	2,200

Figure6-3 Premier Su, Minister Chen and TFDA Director-General Wu visited a pharmacy to inspect the preparation works of Name-Based Mask Distribution System

between February 6 and June 30, 2020, were given subsidy, and a total amount of NT$178,540,000 were distributed. The Executive Yuan also planned to issue epidemic control medals, and TFDA produced individual epidemic control medals for pharmacists and assistant pharmacists as appreciation for the promotion of sales of masks through the Name-Based Mask Distribution System. Certificates of appreciation were also produced and presented to the pharmaceutical professionals who offered their assistance.

II. The Masks Distribution and Sale Big Data Analysis System for closing entries

TFDA used the Masks Distribution and Sale Big Data Analysis System for the closing entries of all sales locations. The System deducted subsidies from the total amount of mask sales (Table 6-3), performing operations such as accounts receivable and payable, verification, billing, and collection. As of December 31, 2020, the accounts receivables from the pharmacies were accumulated 56,633 times, with a total amount of NT$5,170,923,214; 56,632 entries of accounts receivable from the pharmacies were received, with a total of NT$5,170,199,140, representing a collection completion rate of 99.9%, and the collection is ongoing.

From February 19 to May 10, 2020, a total of 3,850,416 bottles of 75% Ethyl Alcohol were delivered to 5,843 pharmacies for sales. Payments for the 75% Ethyl

Table6-3 Subsidy measures for Name-Based Mask Distribution System 1.0

Date	Description	Remark
February 6 to April 8, 2020	NT$800 per day.	Pharmacies packing
April 9 to December 30, 2020	NT$5.5 per person-time.	Pharmacies packing
From December 31, 2020	The original packaging subsidy was changed to the mask service charge for pharmacies, at NT$5 per person-time.	Factories packing

Alcohol were all collected, for a collection rate of 100%.

III. Notification and handling of defective mask

TFDA compiled the number of defective masks and associated manufacturers every week, providing the information to the Industrial Development Bureau of the Ministry of Economic Affairs to guide manufacturers to improve the qualities of masks. For manufacturers notified more than 900 pieces of defective masks, TFDA provided the information of sale location to the Taiwan Textile Research Institute, coordinating the return and exchange of defective masks. As of the end of December 2020, a total of approximately 1,070 reported cases were received, and there were 81 cases of return or exchange. Manufacturers are encouraged to maintain the quality of masks through user feedback and counseling practices.

IV. Actively promoted epidemic control communication

TFDA promoted epidemic control policies on the TFDA Facebook fan page, TFDA LINE@, weekly report on drug and food safety, the Internet, and news tickers of news channels, and in 2020 produced a total of 386 epidemic control messages, of which 164 promoted the Name-Based Mask Distribution System. Also, TFDA made 4 promotional videos on “How to Buy Masks” with the Department of Information Services of the Executive Yuan to be broadcasted on the requisitioned TV channels.