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# 2021 Quasi-Drug Approval Report

April, 2022

MINISTRY OF FOOD AND DRUG SAFETY  
[www.mfds.go.kr](http://www.mfds.go.kr)



Ministry of Food and Drug Safety  
Director for Novel Products Approval







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# 1

## General Status of Quasi-Drug Approval (Notification) in 2021





## 1 General Status of Quasi-Drug Approval (Notification) in 2021

The approval report aims to support the systemization, efficiency of policy establishment, execution, approval and approval/notification procedures and product development by organizing, analyzing and sharing the overall approval and notification status of quasi-drugs manufacturing and import items from various viewpoints.

### 1.1 Overview

Quasi-drugs are defined under subparagraph 7 of Article 2 of the Pharmaceutical Affairs Act and classified into 3 categories. The Minister of Food and Drug Safety designates and announces the scope of such items accordingly.

#### < Pharmaceutical Affairs Act> Subparagraph 7, Article 2

7. The term “quasi-drug” means any of the following articles designated by the Minister of Food and Drug Safety (excluding articles which shall be used for the purposes described in subparagraph 4 (b) or (c)):
- (a) Fibers, rubber products, or similar products used for the purpose of treatment, alleviation, care, or prevention of human or animal diseases;
  - (b) Non-appliance, non-machinery or similar articles that have insignificant influences on or do not directly act upon human bodies;
  - (c) Medication for sterilization, insecticide, and other similar uses for the purpose of preventing infectious diseases;

For application of products as quasi-drug, the products should be subject to marketing approval or notification based on the need for safety and effectiveness examination or availability of process procedures for the products. An item that falls under any of the following categories should be subject to marketing notification:

- O Items which are listed in the Korean Pharmacopoeia or the procedure or formulary accepted by the Minister of Food and Drug Safety, excluding those not approved in Korea.
- O Items of which the standards and test methods are announced by the Minister of Food and Drug Safety
- O Items which meet the standard manufacturing criteria announced by the Minister of Food and Drug Safety.

## 1.2 General Status

The total number of manufacturing, import marketing approvals and notifications for quasi-drugs in 2021 is 5,067 which is an 3.8% increase or 186 from 4,881 in 2020.

Of the total items, the number of manufacturing is 4,881 (96.3%), whereas the number of import is 186 (3.7%), resulting in 26 times higher number of domestically manufactured items than imported ones. The number of approvals stood at 4,454 (87.9%), 7 times higher than that of notifications of 613 (12.1%).

By processing institution, the regional offices were responsible for the largest proportion of marketing approvals and notifications at 5,047 (99.6%) in contrast to 20 (0.4%) by the headquarters. In analysis of regional offices' tasks, the number of approvals was 4,434 (87.9%), while the number of notifications stood at 613 (12.1%).

In addition, when compared the figures of the manufacturing, import approval and notification in 2021 to those in 2020, the number of the overall items approved was 878 (24.6%), with the number of items approved and notified by the regional offices being 219 items (4.5%), and the number of manufacturing and import being 268 (5.8%), which showed an increase compared to a year earlier.

By domestic manufacturing and import for 2021, the domestic manufacturing accounted for the vast majority of the total cases(96.3%), up 1.8% from the last year.

**Table 1** Quasi-drug Manufacturing, Import Marketing Approval and Notification Status (2020-2021)

(Unit: Number of Items)

| Year | Total | Approval         | Notification     | HQ           | Regional Office  | Mfg.             | Import        |
|------|-------|------------------|------------------|--------------|------------------|------------------|---------------|
| 2021 | 5,067 | 4,454<br>(87.9%) | 613<br>(12.1%)   | 20<br>(0.4%) | 5,047<br>(99.6%) | 4,881<br>(96.3%) | 186<br>(3.7%) |
| 2020 | 4,881 | 3,576<br>(73.3%) | 1,305<br>(26.7%) | 53<br>(1.1%) | 4,828<br>(98.9%) | 4,613<br>(94.5%) | 268<br>(5.5%) |

\* Excluding those for export, including those canceled or withdrawn

In 2021, the number of quasi-drug manufacturing, import marketing approvals and notifications stood at 5,067. Based on the yearly comparison of the number of manufacturing, import approvals and notifications over the last 1 decade, the figure was 2,400 during the period of 2013 through 2016,

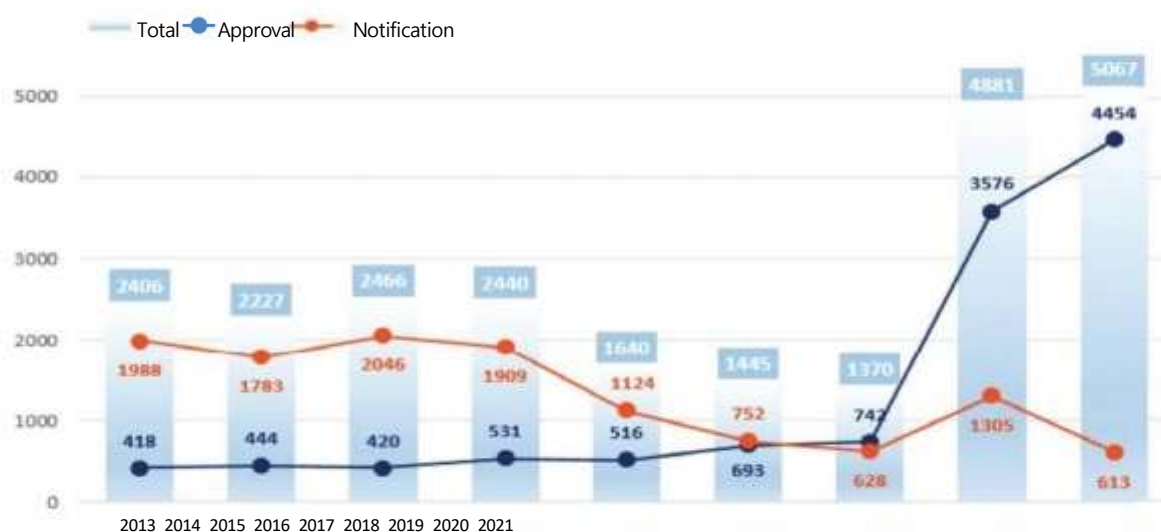
whereas there was a temporary decline to 1,500 during the period of 2017 through 2019 due to transfer to functional cosmetics, followed by a dramatic increase since 2020.

Such a rise is believed to be due to a substantial surge in demand for quasi-drugs (masks and external disinfectants), the quarantine supplies for prevention of infection after the outbreak of the COVID-19 pandemic along with the additional designation of anti-droplet masks for prevention of the droplet infection in daily life in June 2020.

**Table 2** Manufacturing, Import Marketing Approval and Notification Status by Year

(Unit: Number of Items)

| Item                      | 2013  | 2014 | 2015 | 2016  | 2017  | 2018  | 2019         | 2020  | 2021                     |
|---------------------------|-------|------|------|-------|-------|-------|--------------|-------|--------------------------|
| Approval                  | 418   | 444  | 420  | 531   | 516   | 693   | 742          | 3,576 | <b>4,454<br/>(87.9%)</b> |
| (Year-on-year increase %) | 6.2   | -5.4 | 26.4 | -2.8  | 34.3  | 7.1   | 381.9        |       | <b>24.6</b>              |
| Notification              | 1988  | 1783 | 2046 | 1909  | 1124  | 752   | 628          | 1,305 | <b>613<br/>(12.1%)</b>   |
| (Year-on-year increase %) | -10.3 | 14.8 | -6.7 | -41.1 | -33.1 | -16.5 | <b>107.8</b> |       | <b>-53.0</b>             |
| Total                     | 2406  | 2227 | 2466 | 2440  | 1640  | 1445  | 1370         | 4881  | <b>5067</b>              |
| (Year-on-year increase %) | -7.4  | 10.7 | -1.1 | -32.8 | -11.9 | -5.2  | <b>256.3</b> |       | <b>3.8</b>               |

**Fig.1** Status of Manufacturing, Import Marketing Approval and Notification by Year (No. of Items, 2013-2021)

In comparison with the manufacturing and import in 2021, the number of approvals accounted for the largest share of the total manufactured items, at 4,362 (89.4%), whereas the number of approvals of the imported items stood at 92 (49.5%), resulting in an insignificant difference compared to 94 (50.5%) of the notifications.

**Table 3** Marketing Approval and Notification Status by Manufacturing, Import in 2021

(Unit: Number of Items)

| Item         | Total        | Mfg.                    | Import                |
|--------------|--------------|-------------------------|-----------------------|
| Approval     | 4,454        | 4,362<br>(89.4%)        | 92<br>(49.5%)         |
| Notification | 613          | 519<br>(10.6%)          | 94<br>(50.5%)         |
| <b>Total</b> | <b>5,067</b> | <b>4,881<br/>(100%)</b> | <b>186<br/>(100%)</b> |

When it comes to the processing institutions (HQ, regional office) in 2021, the number of approvals by regional offices was 4,434 (99.6%), taking up the largest share of the total approvals of 4,454.

**Table 4** Marketing Approval and Notification Status by Processing Institution in 2021

(Unit: Number of Items)

| Item         | Total        | HQ               | Regional Office      |
|--------------|--------------|------------------|----------------------|
| Approval     | 4,454        | 20 (0.4%)        | 4,434 (99.6%)        |
| Notification | 613          | -                | 613                  |
| <b>Total</b> | <b>5,067</b> | <b>20 (0.4%)</b> | <b>5,047 (99.6%)</b> |

In analysis of the processing status of the regional offices in 2021, with the total number of items processed being 5,047, the numbers of manufacturing and import were 4,886 (96.4%) and 181 (3.6%), respectively.

Of the items manufactured, the approvals accounted for the largest share at 4,362 (89.3%), whereas the notifications were responsible for 94 (51.9%) of the overall items imported, which is slightly higher than those for approval.

**Table 5** Manufacturing, Import Marketing Approval and Notification Status by Processing Institution in 2021

(Unit: Number of Items)

| Manufacturing (4,881 items) |                            | Import (186 items)   |                         |
|-----------------------------|----------------------------|----------------------|-------------------------|
| Approval<br>(4,362)         | HQ<br>(15)                 | Approval<br>(92)     | HQ<br>(5)               |
|                             | Regional Office<br>(4,347) |                      | Regional Office<br>(87) |
| Notification<br>(519)       | Regional Office<br>(519)   | Notification<br>(94) | Regional Office<br>(94) |

In terms of the status of the 6 regional offices, the Gyeongin regional office took up the largest proportion at 2,128 (42.2%), followed by the Daejeon regional office at 897 (17.8%). In other words, the number of items processed by the two regional offices reached 3,025, accounting for 59.9% of the total approvals and notifications.

Table 6 Manufacturing, Import Marketing Approval and Notification by Regional Office of Food and Drug Safety in 2021

(Unit: Number of Items)

| Item            |                          | Approval | Notification | Total    |
|-----------------|--------------------------|----------|--------------|----------|
| Regional Office | Seoul regional office    | 751      | 94           | 845      |
|                 |                          | (16.9%)  | (15.3%)      | (16.7%)  |
|                 | Busan regional office    | 330      | 41           | 371      |
|                 |                          | (7.4%)   | (6.7%)       | (7.4%)   |
|                 | Gyeongin regional office | 1,932    | 196          | 2,128    |
|                 |                          | (43.6%)  | (32.0%)      | (42.2%)  |
|                 | Daegu regional office    | 410      | 46           | 456      |
|                 |                          | (9.2%)   | (7.5%)       | (9.0%)   |
|                 | Gwangju regional office  | 328      | 22           | 350      |
|                 |                          | (7.4%)   | (3.6%)       | (6.9%)   |
|                 | Daejeon regional office  | 683      | 214          | 897      |
|                 |                          | (15.4%)  | (34.9%)      | (17.8%)  |
|                 | Total                    | 4,434    | 613          | 5,047    |
|                 |                          | (87.9%)  | (12.1%)      | (100.0%) |

## 1.3

## Manufacturing, Import Marketing Approval and Notification by Classification Code

By classification code, the marketing approvals and notifications for 2021 showed filtering respirator (55.6%), anti-droplet mask (21.2%), menstrual pad (7.7%), followed by the surgical mask, adhesive bandage, external disinfectant, toothpaste, and mouthwash.

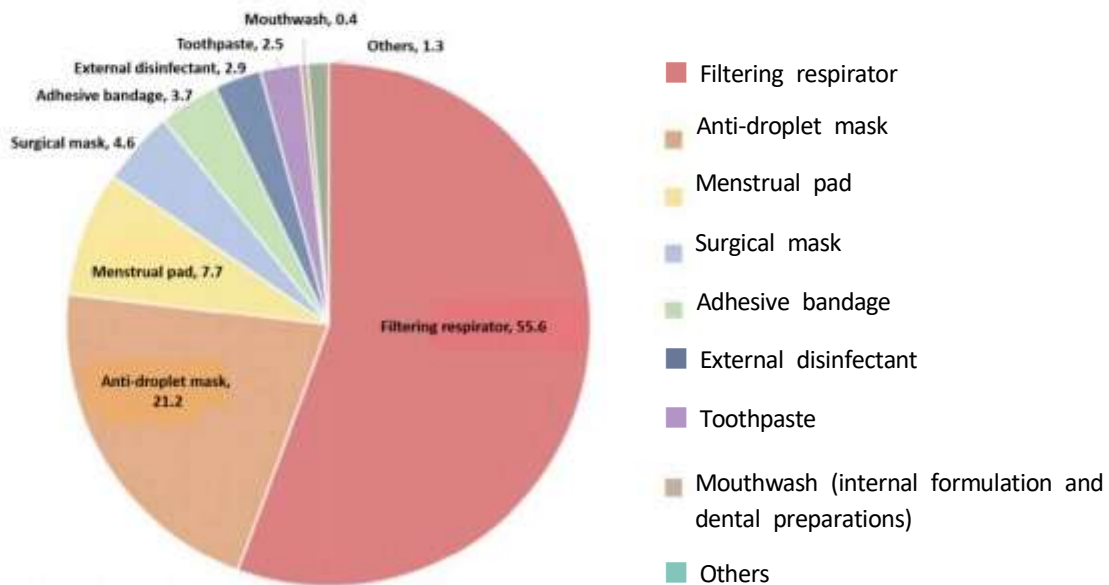
**Table 7** Marketing Approval and Notification by Classification Code in 2021

(Unit: Number of Items)

| Classification Code | Filtering respirator | Anti-droplet mask | Menstrual pad | Surgical mask | Adhesive bandage | External disinfectant | Toothpaste    | Mouthwash    | Others       |
|---------------------|----------------------|-------------------|---------------|---------------|------------------|-----------------------|---------------|--------------|--------------|
|                     | [32200]              | [32300]           | [31100]       | [32100]       | [33800]          | [46000]               | [41400]       | [41100]      |              |
| Total               |                      |                   |               |               |                  |                       |               |              |              |
| 5,067               | 2,819<br>(55.6%)     | 1,076<br>(21.2%)  | 392<br>(7.7%) | 232<br>(4.6%) | 188<br>(3.7%)    | 147<br>(2.9%)         | 128<br>(2.5%) | 19<br>(0.4%) | 66<br>(1.3%) |

**Fig. 2**

Marketing Approval and Notification Distribution by Classification Code in 2021



In comparison with the last year's marketing approval and notification status by classification code, filtering respirators were 55.6% (2,819 items), taking up the largest proportion following 2020. In particular, the marketing approval and notifications for 3 types of quasi-drug masks (filtering respirator, surgical mask, anti-droplet mask) including filtering respirators were responsible for 4,127 or 81.4% of the total items in 2021.

However, when compared to the previous year based on classification code, the year 2021 saw an overall decline with the exception of the filtering respirators. Notably, the external disinfectants experienced the biggest drop (80.5%) down from 608 in 2020 to 147.

**Table 8** Marketing Approval and Notification by Classification Code in 2021 (2020-2021)

(Unit: Number of Items)

| Year | Filtering<br>respirator<br>[32200] | Anti-droplet<br>mask<br>[32300] | Menstrual<br>pad<br>[31100] | Surgical<br>mask<br>[32100] | Adhesive<br>bandage<br>[33800] | External<br>disinfectant<br>[46000] | Toothpaste<br>[41400] | Mouthwash<br>[41100] | Others       | Total |
|------|------------------------------------|---------------------------------|-----------------------------|-----------------------------|--------------------------------|-------------------------------------|-----------------------|----------------------|--------------|-------|
| 2021 | 2,819<br>(55.6%)                   | 1,076<br>(21.2%)                | 392<br>(7.7%)               | 232<br>(4.6%)               | 188<br>(3.7%)                  | 147<br>(2.9%)                       | 128<br>(2.5%)         | 19<br>(0.4%)         | 66<br>(1.3%) | 5,067 |
| 2020 | 1,651<br>(33.8%)                   | 1,214<br>(24.9%)                | 436<br>(8.9%)               | 408<br>(8.4%)               | 128<br>(2.6%)                  | 755<br>(15.5%)                      | 204<br>(4.2%)         | 17<br>(0.3%)         | 68<br>(1.4%) | 4,881 |



**Table 9** Detailed Status of Marketing Approval and Notification by Classification Code in 2021

| Item                           | Classification Code |  | No. of Items |
|--------------------------------|---------------------|--|--------------|
| Item A*                        | 3110                | Menstrual Pad  | 392          |
|                                | 3120                | Menstrual Tampon   | 5            |
|                                | 3130                | Menstrual Cup  | 5            |
|                                | 3210                | Surgical Mask  | 232          |
|                                | 3220                | Filtering Respirator   | 2,819        |
|                                | 3230                | Anti-droplet mask  | 1,076        |
|                                | 3310                | Eye Mask   | 2            |
|                                | 3330                | Elastic Bandage  | 5            |
|                                | 3360                | Gauze  | 5            |
|                                | 3370                | Absorbent Cotton   | 8            |
|                                | 3380                | Adhesive Bandage   | 188          |
|                                | Subtotal            |  | 4,737        |
| Item B**                       | 4110                | Mouthwash (internal formulation and dental preparations)   | 19           |
|                                | 4130                | Anti miliaria, anti-inflammation products  | 1            |
|                                | 4140                | Toothpaste   | 128          |
|                                | 4320                | Repellent  | 4            |
|                                | 4400                | Contact Lens Care Product  | 5            |
|                                | 4600                | External Disinfectant  | 147          |
|                                | 4711                | Ointment   | 2            |
|                                | 4713                | Spray Patch  | 1            |
|                                | 4721                | Low-content Vitamin and Mineral Agent  | 9            |
|                                | 4722                | Nutrients, Tonic and Alternatives(internal liquid formulation only)  | 2            |
|                                | 4840                | Teeth Whitening Solution   | 1            |
|                                | 4850                | Preparation for cleaning and disinfecting denture(false teeth), dental braces and other removable oral devices | 2            |
|                                | Subtotal            |  | 321          |
| Items similar to Items A and B | 3500                | Other similar products   | 8            |
|                                | 4920                | Portable product containing air composition or oxygen manufactured to be breathed in by person                 | 1            |
|                                | Subtotal            |  | 9            |
| Total                          |                     |  | 5,067        |

\* Item A : items falling under subparagraph 7 (a) of Article 2 of the Pharmaceutical Affairs Act

\*\* Item B : items falling under subparagraph 7 (b) of Article 2 of the Pharmaceutical Affairs Act



# 2

## **Detailed Status of Quasi-Drug Approval in 2021**



## 2 Detailed Status of Quasi-Drug Approval in 2021

Quasi-drugs are largely classified into items that fall under subparagraph 7 (a) or (b) of Article 2 of Pharmaceutical Affairs Act (hereinafter Item A or B), and items subject to safety and effectiveness examination or items not subject to safety and effectiveness examination depending on the type of examination.

Of the total marketing approvals of 4,454 in 2021, Item A was responsible for the largest share at 4,367 (98.0%), followed by Item B at 79 (1.8%) and others similar to Items A and B at 8 (0.2%). This is a similar proportion to the year of 2020.

When it comes to the safety and effectiveness examination, the number of items approved subject to the examination was 20, which included 15 items (75.0%) of manufacturing and 5 items(25.0%) of import. This represents a 43.4% (23) fall in comparison with 53 items in 2020.

When analyzing the approved 20 items subject to safety and effectiveness examination in 2021 by item, Item A was 8 (4 filtering respirators, 3 menstrual cups, 1 menstrual pad), Item B was 10 (6 toothpastes, 2 external disinfectants, 2 mouthwashes) and others similar to Items A and B was 2 (2 maternity pads).

**Table 10-1** Marketing Approval and Notification by Classification Code in 2021 (2020-2021)

(Unit: Number of Items)

| Year | Total | Item A           | Item B       | ItemC* | Similar Items A and B |
|------|-------|------------------|--------------|--------|-----------------------|
| 2021 | 4,454 | 4,367<br>(98.0%) | 79<br>(1.8%) | -      | 8<br>(0.2%)           |
| 2020 | 3,576 | 3,479<br>(97.3%) | 89<br>(2.5%) | -      | 8<br>(0.2%)           |

\* Insecticides for infectious disease prevention which fall under Items C and B of Subparagraph 7 of Article 2 of the Pharmaceutical Affairs Acts was transferred to the Ministry of Environment as of Jan. 1, 2019.

**Table 10-2** Status of Marketing Approval Subject to Manufacturing, Import Safety and Effectiveness Examination (2020-2021)

(Unit: Number of Items)

| Item | Total | Manufacturing | Import    |
|------|-------|---------------|-----------|
| 2021 | 20    | 15 (75.0%)    | 5 (25.0%) |
| 2020 | 53    | 46 (86.8%)    | 7 (13.2%) |

**Table 10-3** Status of Marketing Approval Subject to Safety and Effectiveness Examination by Item in 2021

| No. | Types  | Item Classification    | Number of Approval Items |
|-----|--|------------------------|--------------------------|
| 1   | Item A                                       | Menstrual Pad          | 1                        |
|     |  | Menstrual Cup          | 3                        |
|     |  | Filtering Respirator   | 4                        |
| 2   | Item B                                       | Mouthwash              | 2                        |
|     |  | Toothpaste             | 6                        |
|     |  | External Disinfectant  | 2                        |
| 3   | Items similar to Items 2 A and B quasi-drugs | Other similar products |                          |

## 2.1 Item A Quasi-Drug Approval Status

Item A quasi-drugs mean products that are made of textile, rubber used for the purpose of treating, alleviating, treating or preventing the disease of humans or animals, and items similar to such products such as masks, menstrual pads and gauzes, etc.

In terms of the marketing approval status of Item A quasi-drug in 2021, the filtering respirators accounted for the largest number of approvals at 2,819 (64.6%), followed by anti-droplet masks at 1,076 (24.6%), surgical masks at 232 (5.3%) and menstrual pads at 149 (3.4%).

**Table 11** Marketing Approval Status of Item A Quasi-Drug in 2021

| Item   |                      | Marketing Approval (Number) |
|--|----------------------|-----------------------------|
| Menstrual Hygiene Management Products                                | Menstrual Pad        | 149                         |
|  | Menstrual Cup        | 5                           |
| Masks  | Surgical Mask        | 232                         |
|  | Filtering Respirator | 2,819                       |
|  | Anti-droplet mask    | 1,076                       |
| Items used for preservation, protection, treatment of affected areas | Eye Mask             | 2                           |
|  | Elastic Bandage      | 5                           |
|  | Gauze                | 1                           |
|  | Adhesive Bandage     | 78                          |
| Total  |                      | 4,367                       |

## 1) Mask

The quasi-drug masks are classified into 3 types after the additional designation of anti-droplet masks in June 2020. The number of items approved in 2021 was 4,127 (2,819 for filtering respirators, 1,076 for anti-droplet masks and 232 for surgical masks).

Of the items approved in 2021, 4 filtering respirators were subject to the safety and effectiveness examination. Referentially, the number of quasi-drug masks subject to the safety and effectiveness examination decreased by 34 compared to 38 in the previous year.

**Table 12** Status of Marketing Approval Subject to Safety and Effectiveness Examination of Mask in 2021

| No. | Mfg./ Import | Product   | Company | Date of Approval | Classification Code             | Remarks         |
|-----|--------------|---|---------|------------------|---------------------------------|-----------------|
| 1   | Mfg.         | Prokeeper Star Mask (KF94)<br>(Medium)  | YONWOO  | Sept/17/2021     | [32200]<br>Filtering Respirator | New application |
| 2   | Mfg.         | Prokeeper Herringbone Mask (KF94)<br>(Medium)                                     | YONWOO  | Sept/23/2021     | [32200]<br>Filtering Respirator | New application |
| 3   | Mfg.         | ezPharm Medical Mask Lite Plus<br>[KF94] ( Large , Medium , Small ) ( White )     | JPC     | Dec/13/2021      | [32200]<br>Filtering Respirator | New efficacy    |
| 4   | Mfg.         | ezPharm Yellow Dust Mask Lite Plus<br>[KF80] ( Large , Medium , Small ) ( White ) | JPC     | Dec/13/2021      | [32200]<br>Filtering Respirator | New efficacy    |

\*To see the approved conditions for each of these products (efficacy, effectiveness, dosage regimen, precautions), visit <http://nedrug.mfds.go.kr>.



## 2) Menstrual Hygiene Management Product

Menstrual hygiene management products include menstrual pads, menstrual tampons and menstrual cups. The number of items approved in 2021 was 154 (149 menstrual pads, 5 menstrual cups).

Among them, the number of items subject to the safety and effectiveness examination was 4 (2 menstrual pads, 2 menstrual cups).

For the menstrual hygiene management products in 2021, the safety and effectiveness examination was conducted under categories of new material (2) and new application(2).

**Table 13**

Status of Marketing Approval Subject to Safety and Effectiveness Examination of Menstrual Hygiene Management Product in 2021

| No. | Mfg./ Import | Product  | Company          | Date of Approval | Classification Code   | Remarks         |
|-----|--------------|--|------------------|------------------|-----------------------|-----------------|
| 1   | Mfg.         | EZcup  | ShinsungSilicone | June/4/2021      | [31300] Menstrual Cup | New application |
| 2   | Mfg.         | 1. Cyclean Hiphugger Air Period Panty ( Blank),<br>2. Cyclean Hiphugger Air Period Panty ( LightPink ) | Cyclean          | June/14/2021     | [31100] Menstrual Pad | New Material    |
| 3   | Mfg.         | Poicup   | TaeJinSilicone   | Sept/6/2021      | [31300] Menstrual Cup | New Material    |
| 4   | Mfg.         | Morecup  | ShinsungSilicone | Oct/12/2021      | [31300] Menstrual Cup | New application |

\* To see the approved conditions for each of these products (efficacy, effectiveness, dosage regimen, precautions), visit <http://nedrug.mfds.go.kr>.

## 2.2

## Item B Quasi-Drug Approval Status

Item B quasi-drugs mean non-appliances, non-machineries or similar articles that have insignificant influences on or do not directly act upon human bodies including external disinfectant, toothpaste or mouthwash, etc.

In terms of the marketing approval status of Item B quasi-drugs in 2021, the external disinfectants were responsible for the highest number of approvals with 43 items (54.4%), followed by toothpaste with 28 items(35.4%) and mouthwashes with 3 items(3.8%).

**Table 14** Marketing Approval Status of Item B Quasi-Drug in 2021

| By item   |   | Marketing Approval (Number) |
|---|---|-----------------------------|
| Preventive Oral Care Product  | Mouthwash                                 | 3                           |
|   | Anti miliaria, anti-inflammation products | 1                           |
|   | Toothpaste                                | 28                          |
| Contact Lens Care Product   |   | 1                           |
| External Disinfectant   |   | 43                          |
| Teeth Whitening Solution  |   | 1                           |
| Preparation for cleaning and disinfecting denture (false teeth), dental braces and other removable oral devices |   | 2                           |
| <b>Total</b>  |   | <b>79</b>                   |

## 1) External Disinfectant

External disinfectants, containing hydrogen peroxide, isopropyl alcohol, benzalkonium chloride, cresol or ethanol directly used for human body, have been designated as quasi-drugs and the number of items approved in 2021 was 43.

Of the items approved in 2021, the number of products subject to the safety and effectiveness examination was 2.

**Table 15** Status of Marketing Approval Subject to Safety and Effectiveness Examination of External Disinfectant in 2021

| No. | Mfg./ Import | Product   | Company    | Date of Approval | Classification Code              | Remarks |
|-----|--------------|---|------------|------------------|----------------------------------|---------|
| 1   | Mfg.         | Clean Care+ Sterilize Wipes (Ethanol)   | ATBIOPHARM | Aug/17/2021      | [46000]<br>External Disinfectant | -       |
| 2   | Mfg.         | 1. Dermatips Save My hand Sanitizer Cream (Ethanol) (Green Tea Scent)<br>2. Dermatips Save My hand Sanitizer Cream (Ethanol) (Cherry Scent)<br>3. Dermatips Save My hand Sanitizer Cream (Ethanol) (Herb Scent) | Sewha P&C  | Dec/16/2021      | [46000]<br>External Disinfectant | -       |

- To see the approved conditions for each of these products (efficacy, effectiveness, dosage regimen, precautions), visit <http://nedrug.mfds.go.kr>.

## 2) Preventive Oral Care Product

The preventive oral care products include toothpastes, mouthwashes and anti miliaria, anti-inflammation products, and 32 items (28 toothpastes, 3 mouthwashes, 1 anti miliaria, anti-inflammation product) received marketing approval in 2021.

Of the items approved in 2021, the number of items subject to the safety and effectiveness examination was 8 (6 toothpastes, 2 mouthwashes).

For the preventive oral care products, the safety and effectiveness examination was implemented based on the criteria of a complex with new composition (4), complex with content variation(3) and new formulation(1).

Table 16

Status of Marketing Approval Subject to Safety and Effectiveness Examination of Preventive Oral Care Product in 2021

| No. | Mfg./ Import | Product  | Company                                   | Date of Approval | Classification Code   | Remarks                        |
|-----|--------------|--|---|------------------|-----------------------|--------------------------------|
| 1   | Mfg.         | 2080 strawberry Flavor Gargle  | Aekyung Industrial Co.,Ltd                | Jan/20/2021      | [41100]<br>Mouthwash  | Complex with content variation |
| 2   | Mfg.         | GUM toothpaste   | Amorepacific                              | March/4/2021     | [41400]<br>Toothpaste | Complex with new composition   |
| 3   | Import       | 1. Perioe Professional Total Protection Great Refreshing Flavor Alpha Plus<br>April/30/2021 Perioe Professional Total Protection Icy Blast Mint Alpha Plus | LG H&H Co.,Ltd                            |                  | [41400]<br>Toothpaste | Complex with content variation |
| 4   | Import       | Logodent Happy Kids Strawberry Tooth Gel (silicon dioxide)   | W Networks                                | July/20/2021     | [41400]<br>Toothpaste | New formulation                |
| 5   | Import       | WeLEDA Salt Toothpaste   | Weleda Korea                              | July/26/2021     | [41400]<br>Toothpaste | Complex with new composition   |
| 6   | Mfg.         | MDF toothpaste   | Amorepacific                              | Aug/6/2021       | [41400]<br>Toothpaste | Complex with new composition   |
| 7   | Import       | Listerine Nightly Reset  | Johnson & Johnson Consumer Health Korea   | Aug/12/2021      | [41100]<br>Mouthwash  | Complex with content variation |
| 8   | Import       | SENSODYNE Original Plus Toothpaste (Eucalyptus Scent)  | GlaxoSmithKline Consumer Healthcare Korea | Nov/9/2021       | [41400]<br>Toothpaste | Complex with new composition   |

- To see the approved conditions for each of these products (efficacy, effectiveness, dosage regimen, precautions), visit <http://nedrug.mfds.go.kr>.

## 23

## Approval Status of Quasi-Drugs Similar to Items A and B

Quasi-drugs similar to Items A and B are quasi-drugs corresponding to subparagraph 4 of 「Designation of Scope of Quasi-drugs」 (Notice of Ministry of Food and Drug Safety) including ▲non-adhesive items used to absorb exudate of the affected area, ▲sterilized items used for surgical treatment for the purpose of infection prevention, ▲wet tissues for mouth cleaning, ▲items used for temporarily adjusting the color of teeth by applying on the tooth surface, ▲portable products containing air composition or oxygen manufactured to be breathed in by person before/after hiking or workout, ▲ items used for sanitization of bleeding immediately after childbirth and lochia (vaginal discharge after childbirth) (commonly called 'maternal pad'), ▲items similar to Item A under subparagraph 7 of Article 2 of Pharmaceutical Affairs Act.

Referentially, the items used for sanitization of bleeding immediately after childbirth and lochia (vaginal discharge after childbirth) were additionally designated to preemptively ensure the consumer safety (Sept. 30, 2019 amended, Oct. 01, 2021, enforced). In 2021, 2 items were among the first to be approved for the safety and effectiveness examination for the efficacy group aforementioned.

Additionally, 6 items including sterilization products (2), portable items (1) obtained marketing approval.

**Table 17** Marketing Approval Status of Quasi-Drugs Similar to Items A and B in 2021

| By item  | Marketing Approval<br>(Number) |
|--|--------------------------------|
| Non-adhesive items used to absorb exudate of the affected area   | 3                              |
| Sterilized items use for surgical treatment for the purpose of infection prevention  | 2                              |
| Items used for sanitization of bleeding immediately after childbirth and lochia (vaginal discharge after childbirth)           | 2                              |
| Portable products containing air composition or oxygen manufactured to be breathed in by person before/after hiking or workout | 1                              |
| <b>Total</b>   | <b>8</b>                       |

Table 18

Status of Marketing Approval Subject to Safety and Effectiveness Examination of Maternity Pad in 2021

| No. | Mfg./ Import | Product                 | Company                | Date of Approval | Classification Code               | Remarks      |
|-----|--------------|-------------------------|------------------------|------------------|-----------------------------------|--------------|
| 1   | Mfg.         | DEPEND Mom's Anshim Pad | Yuhan-Kimberly, Limitd | Nov/15/2021      | [35000]<br>Other similar products | New efficacy |
| 2   | Mfg.         | DEPEND Mom's Anshim     | Yuhan-Kimberly, Limitd | Nov/22/2021      | [35000]<br>Other similar products | New efficacy |

\*To see the approved conditions for each of these products (efficacy, effectiveness, dosage regimen, precautions), visit <http://nedrug.mfds.go.kr>.

3

## Quasi-Drug Approval Trend





### 3 Quasi-Drug Approval Trend

#### 3.1 Status of Quasi-Drug Approval Management

The scope of the quasi-drug designation has been continuously expanded to preemptively ensure the safety of consumers.

The insecticides for infection control, one of the dominant items obtained the marketing approval in 2018 were transferred to items under the jurisdiction of the Act according to enactment of 「Act on Safety Management of Household Chemicals and Biocides」 (Jan. 1, 2019), and managed as a biocidal product.

The items used for sanitization of bleeding immediately after childbirth and lochia(vaginal discharge after childbirth) were additionally designated as a quasi-drug in 2019, and 2 items were approved in 2021 for the first time.

The anti-droplet masks were newly added to the list of quasi-drugs (June 1, 2020) for infection prevention due to the outbreak of COVID-19 pandemic in 2020. The Methods of Examinations and Standards for Quasi-drugs was amended to incorporate the standard specifications of the materials for mask manufacturing (plastic nose bridges and ear straps).

A consistent effort will be made to support the product development through addition of standardized finished mask products and standard specifications of raw materials.

### 3.2 Quasi-Drug Approval Trend and New Quasi-drug Approval in 2021

The Manufacturing, Import Marketing Approval and Notification Status after 2018 was predominantly represented by filtering respirators, anti-droplet masks and external disinfectants.

The menstrual pads with enhanced convenience have been responsible for the largest number of approvals owing to various lifestyles of consumers until 2019, which was overtaken by face masks after COVID-19 pandemic in 2020.

In 2020, the number of new marketing approvals for masks (filtering respirators, anti-droplet masks, surgical masks) and external disinfectants dramatically increased to 3,325, taking up 93% of the total approvals of 3,576.

In 2021, amid the ongoing COVID-19 pandemic, the number of the new marketing approvals for face mask products, an essential infection control product, rose by 802 to 4,127 or 81.4% of the total 5,067, compared to a year earlier.

In the meantime, 2 maternity pads obtained the first quasi-drug marketing approval as an 'item used for sanitization of bleeding immediately after childbirth and lochia (vaginal discharge after childbirth)' in 2019.

**Table 19** Marketing Approval Status of Maternity Pads in 2021

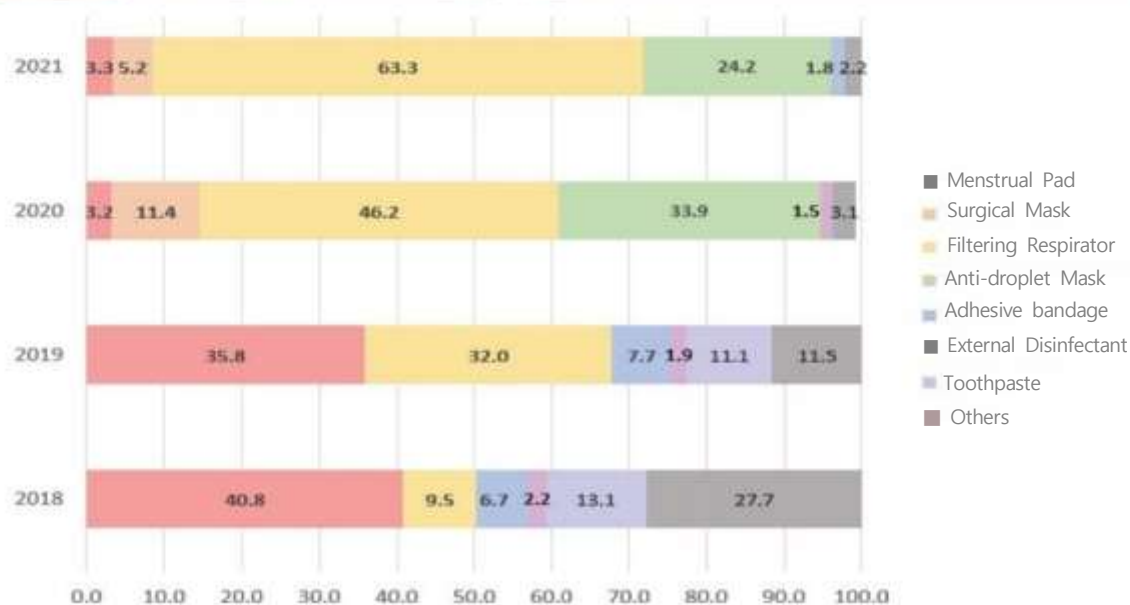
| No. | Mfg./Import | Product                        | Company        | Date of Approval |
|-----|-------------|--------------------------------|----------------|------------------|
| 1   | Mfg.        | Defend Mom's Relief Pad        | Yuhan Kimberly | Nov/15/2021      |
| 2   | Mfg.        | Defend Mon's Relief Panty Type | Yuhan Kimberly | Nov/22/2021      |

**Table 20** Status of Marketing Approval of Top 5 Products (Classification Code) by Year (2018-2021)

| No.                         | 2018                                      |              | 2019                          |              | 2020                          |               | 2021                          |               |
|-----------------------------|---|--------------|-------------------------------|--------------|-------------------------------|---------------|-------------------------------|---------------|
|                             | Efficacy (ClassificationCode)             | No.ofitems   | Efficacy (ClassificationCode) | No.ofitems   | Efficacy (ClassificationCode) | No.ofitems    | Efficacy (ClassificationCode) | No.ofitems    |
| 1                           | Menstrual Pad (3110)                      | 590 (40.8%)  | Menstrual Pad (3110)          | 491 (35.8%)  | Filtering Respirator (3220)   | 1,651 (46.2%) | Filtering Respirator (3220)   | 2819 (63.3%)  |
| 2                           | Toothpaste (4140)                         | 189 (13.1%)  | Filtering Respirator (3220)   | 439 (32.0%)  | Anti-droplet mask** (3230)    | 1,214 (33.9%) | Anti-droplet mask (3230)      | 1,076 (24.2%) |
| 3                           | Insecticide for Infection Control* (5110) | 164 (11.3%)  | Toothpaste (4140)             | 152 (11.1%)  | Surgical Mask (3210)          | 408 (11.4%)   | Menstrual Pad (3110)          | 149 (3.3%)    |
| 4                           | Filtering Respirator (3220)               | 137 (9.5%)   | Adhesive Bandage (3380)       | 105 (7.7%)   | Menstrual Pad (3110)          | 114 (3.2%)    | Surgical Mask (3210)          | 232 (5.2%)    |
| 5                           | Adhesive Bandage (3380)                   | 97 (6.7%)    | External Disinfectant (4600)  | 26 (1.9%)    | External Disinfectant (4600)  | 52 (1.5%)     | Adhesive Bandage (3380)       | 78 (1.8%)     |
| Marketing Approval (Number) |   | 1,445 (100%) |                               | 1,370 (100%) |                               | 3,576 (100%)  |                               | 4,454 (100%)  |

\* Transferred to the Ministry of Environment as of Jan 01,2019

\*\* Additionally designated as quasi-drugs as of June 01,2020

**Fig. 3** Marketing Approval Percentage by Quasi-Drug Classification Code and Year (2018-2021)



# 4

## Appendix



## Appendix

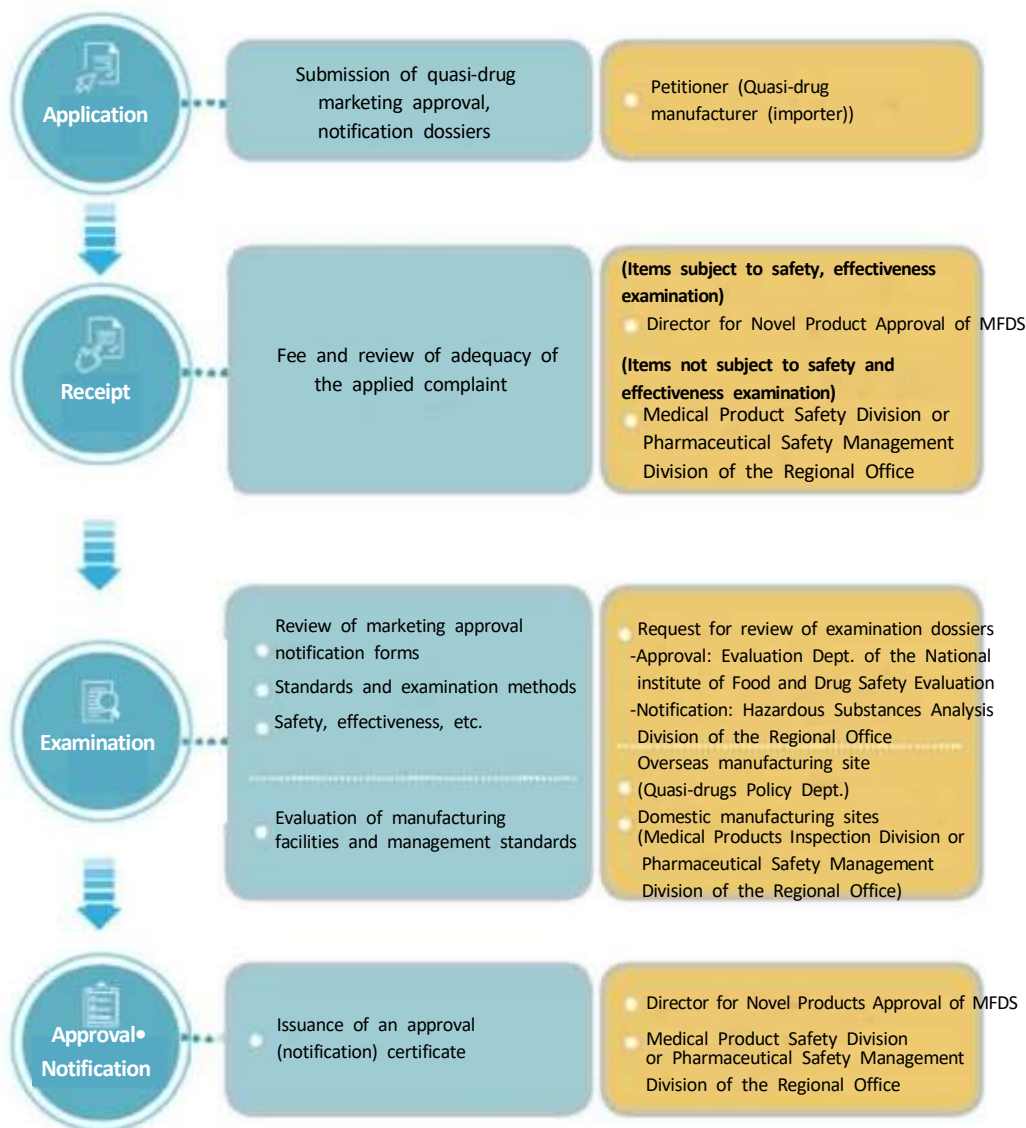
## Departments Handling Quasi-Drug Complaints

Table 21 Departments Handling Quasi-drug Complaints (As of April, 2022)

| Item  | Department   | Detailed Petition Service   |
|---|--|---|
| Director for Novel Products Approval                  |  | Quasi-drug manufacturing, import marketing approval (including change)<br>• Items subject to safety and effectiveness examination only                            |
| Biopharmaceuticals and Herbal Medicine Bureau         | Quasi-drugs Policy Dept.   | Quasi-drug designation-classification and GMP evaluation  |
| National Institute of Food and Drug Safety Evaluation | Biopharmaceuticals and Herbal Medicine Evaluation Dept.<br>Cosmetics Evaluation Division | Quasi-drugs<br>• Safety and effectiveness examination<br>• Evaluation of standards and examination methods<br>• Preview   |
| Seoul Regional Office of Food and Drug Safety         | Pharmaceutical Safety Management Division  |   |
| Gyeongin Regional Office of Food and Drug Safety      |  |   |
| Daejeon Regional Office of Food and Drug Safety       |  |   |
| Busan Regional Office of Food and Drug Safety         | Medical Product Safety Division  | Quasi-drug manufacturing, import marketing approval and notification (including change)<br>• Limited to items not subject to safety and effectiveness examination |
| Daegu Regional Office of Food and Drug Safety         |  |   |
| Gwangju Regional Office of Food and Drug Safety       |  |   |

# Appendix Procedure of Quasi-drug Manufacturing (Import) Marketing Approval (Notification)

Fig. 4 Procedure of Quasi-drug Manufacturing (Import) Marketing Approval (Notification)





## Appendix Status of Quasi-Drug Approval and Notification

**Table 22** Status of Manufacturing, Import Marketing Approval and Notification of Quasi-drugs(2018-2021)

(Unit: Number of Items)

| Year | Total | Approval         | Notification     | HQ             | Regional Office  | Mfg.             | Import         |
|------|-------|------------------|------------------|----------------|------------------|------------------|----------------|
| 2021 | 5,067 | 4,454<br>(87.9%) | 613<br>(12.1%)   | 20<br>(0.4%)   | 5,047<br>(99.6%) | 4,881<br>(96.3%) | 186<br>(3.7%)  |
| 2020 | 4,881 | 3,576<br>(73.3%) | 1,305<br>(26.7%) | 53<br>(1.1%)   | 4,828<br>(98.9%) | 4,613<br>(94.5%) | 268<br>(5.5%)  |
| 2019 | 1,370 | 742<br>(54.2%)   | 628<br>(45.8%)   | 28<br>(2.0%)   | 1,342<br>(98.0%) | 1,178<br>(86.0%) | 192<br>(14.0%) |
| 2018 | 1,445 | 693<br>(48.0%)   | 752<br>(52.0%)   | 229<br>(15.8%) | 1,216<br>(84.2%) | 1,233<br>(85.3%) | 212<br>(14.7%) |

\* Excluding those for export, including those canceled or withdrawn

**Table 23** Status of Marketing Approval and Notification by Classification Code(2018-2021)

(Unit: Number of Items)

| Year  | Filtering<br>Respirator<br>[32200] | Anti-droplet<br>mask<br>[32300] | Menstrual<br>Pad<br>[31100] | Surgical<br>Mask<br>[32100] | Adhesive<br>Bandage<br>[33800] | External<br>Disinfectant<br>[46000] | Toothpaste<br>[41400] | Mouthwash<br>[41100] | Others         | Total |
|-------|------------------------------------|---------------------------------|-----------------------------|-----------------------------|--------------------------------|-------------------------------------|-----------------------|----------------------|----------------|-------|
| 2021  | 2,819<br>(55.6%)                   | 1,076<br>(21.2%)                | 392<br>(7.7%)               | 232<br>(4.6%)               | 188<br>(3.7%)                  | 147<br>(2.9%)                       | 128<br>(2.5%)         | 19<br>(0.4%)         | 66<br>(1.3%)   | 5,067 |
| 2020  | 1,651<br>(33.8%)                   | 1,214<br>(24.9%)                | 436<br>(8.9%)               | 408<br>(8.4%)               | 128<br>(2.6%)                  | 755<br>(15.5%)                      | 204<br>(4.2%)         | 17<br>(0.3%)         | 68<br>(1.4%)   | 4,881 |
| *2019 | 439<br>(32.0%)                     | -                               | 491<br>(35.8%)              | 22<br>(1.6%)                | 105<br>(7.7%)                  | 26<br>(1.9%)                        | 152<br>(11.1%)        | 12<br>(0.9%)         | 123<br>(9.0%)  | 1,370 |
| *2018 | 137<br>(9.5%)                      | -                               | 590<br>(40.8%)              | 29<br>(2.0%)                | 97<br>(6.7%)                   | 32<br>(2.2%)                        | 189<br>(13.1%)        | 8<br>(0.6%)          | 363<br>(25.1%) | 1,445 |

## 2021 Quasi-Drug Approval Report

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