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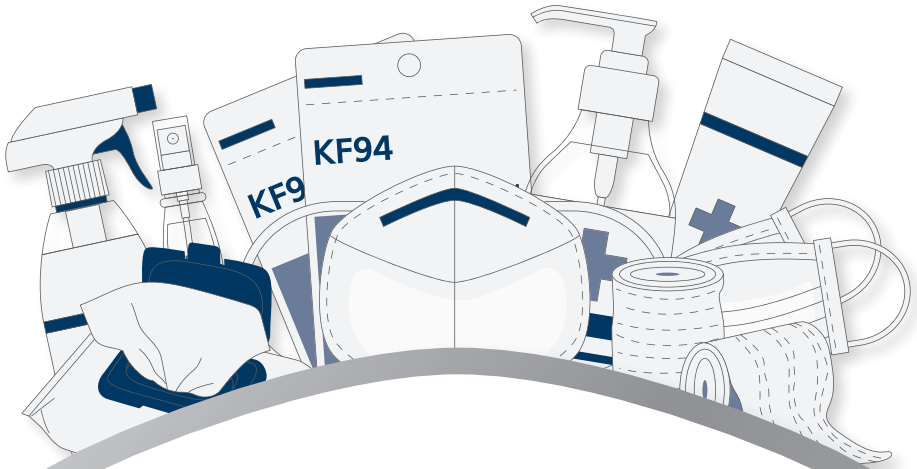

2020

Quasi-Drug Approval Report

June, 2021

Ministry of Food and Drug Safety

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Ministry of Food and Drug Safety

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General Status of Quasi-Drug Approval[Notification] in 2020

01 General Status of Quasi-Drugs Approval[Notification] in 2020

The 2020 approval report aims to support systematic, effective arrangement of policy establishment, execution, approval and reporting tasks and development of products by sorting, analyzing and sharing the overall approval and report status of quasi-drugs manufacturing and import items from various viewpoints.

1.1. Overview

Quasi-drugs are defined in subparagraph 7, Article 2 of the Pharmaceutical Affairs Act and divided into 3 types. 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 prescribed in subparagraph 4 (b) or (c)):
   (a) Fibers, rubber products or similar products used for the purpose of treating, alleviating, or preventing 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) Preparations used for sterilization, insecticide, and uses similar thereto for the purpose of preventing infectious diseases;

For application of products as quasi-drug, the products are classified into the target for marketing approval or marketing notification depending on whether they are subject to safety and effectiveness examination or there are process procedures for the product. The following cases are defined as the targets for marketing notification.

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

1.2. General Status

In 2020, there were 4,881 cases of manufacturing, import marketing approval and notification as the quasi-drugs and the total number of quasi-drugs increased by 3,511 items(256.3%) compared to 2019.

Among the total items, there were 4,613 items of manufacturing(94.5%), 268 items of import(5.5%), which indicates that the number of manufacturing items was 17 times higher. There were 3,576 items of approval(73.3%) and 1,305 items of notification(26.7%), which indicates that the number of marketing approval is 3 times higher.

In addition, by processing institutions, the approval from the headquarter was 53 items(1.1%); approval and notification from regional office was 4,828 items(98.9%), showing that most of them were processed by the regional office. In particular, by comparison with marketing approval item only, the approval from the local government was high as 3,523 items(98.5%), which indicates that the

percentage of items not subject to safety and effectiveness was higher among approval items.

In addition, when comparing the present status of manufacturing, import marketing approval and notification for 2020 with those for 2019, the approval items were 2,834 items(381.9%), approval and notification items for regional office were 3,486 items(259.8%), manufacturing items were 3,435 items(291.6%), showing significant increase. In particular, manufacturing items were higher not only in numbers but also in percentage as 94.5%, showing increase over 8.5% compared to 2019.

Table 1 Quasi-drug Manufacturing, Import Marketing Approval and Notification Status (2019-2020)

(Unit: Number of Items)

Year	Total	Approval	Notification	HQ	Regional office	Mfg.	Import
2020	**4,881**	**3,576 (73.3%)**	**1,305 (26.7%)**	**53 (1.1%)**	**4,828 (98.9%)**	**4,613 (94.5%)**	**268 (5.5%)**
2019	**1,370**	742 (54.2%)	628 (45.8%)	28 (2.0%)	1,342 (98.0%)	1,178 (86.0%)	192 (14.0%)

* Excluding those for export, including those cancelled or withdrawn

In 2020, the number of quasi-drugs manufacturing, import marketing approval and notification items increased about 256.3%(4,881 items) compared to 1,370 items in 2019. Among them, the approval items increased 381.9%(2,834 items) and notification items increased 107.8%(677 items) compared to previous year.

When comparing the number of items for manufacturing, import marketing approval and notification by year since 2012, it showed rapid increase in 2020. It seems to be attributable to worldwide COVID-19 pandemic, which substantially increased demand of quasi-drugs(external disinfectant and mask), the quarantine supplies for prevention of infection. In June 2020, anti-droplet mask used for prevention of droplet infection in daily life, was additionally designated as the quasi-drug mask, resulting in increase and diversification of quasi-drugs mask into 3 types. This caused rapid increase in number of new items for manufacturing, import marketing approval and notification.

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

(Unit: number of items)

Classification	2012	2013	2014	2015	2016	2017	2018	2019	2020
Approval	453	418	444	420	531	516	693	742	**3,576 (73.2%)**
(Year-on-year increase %)		-7.7	6.2	-5.4	26.4	-2.8	34.3	7.5	**381.9**
Notification	1959	1988	1783	2046	1909	1124	752	628	**1,305 (26.8%)**
(Year-on-year increase %)		1.5	-10.3	14.8	-6.7	-41.1	-33.1	-16.4	**107.8**
Total	2412	2406	2227	2466	2440	1640	1445	1370	**4,881**
(Year-on-year increase %)		-0.2	-7.4	10.7	-1.1	-32.8	-11.9	-4.9	**256.3**

* Excluding those for export, including those cancelled or withdrawn

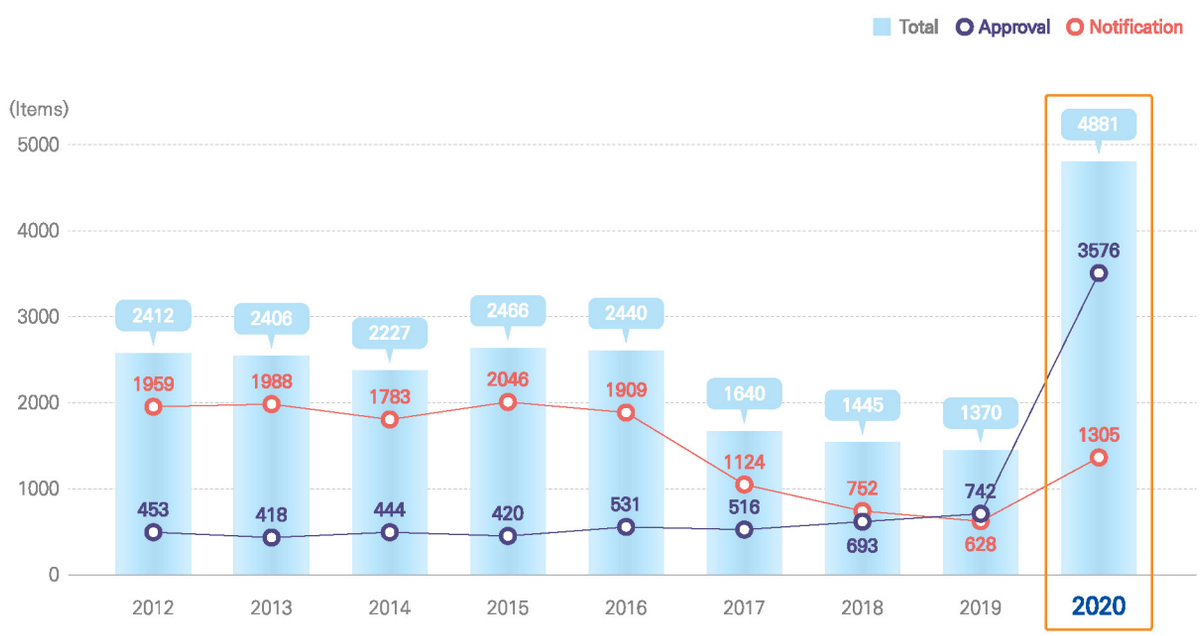

Fig. 1 Number of Items for Manufacturing, Import Marketing Approval and Notification by Year (2012-2020)

When classifying manufacturing, import marketing approval and notification status for 2020 by processing institutions (HQ, regional office), out of total approval items of 3,576, items for approval by regional office were 3,523 items(98.5%), 66 times higher than the approval items by HQ, 53 times(1.5%). This indicates that the items not subject to safety and effectiveness examination, to be approved by regional office has absolute advantage over the approval subject to safety and effectiveness examination, to be approved by HQ.

Table 3 Marketing Approval and Notification Status by Processing Institution in 2020

(Unit: number of items)

Classification	Total	HQ	Regional office
Approval	**3,576**	53 (1.5%)	3,523 (98.5%)
Notification	**1,305**	-	1,305
Total	**4,881**	**53 (1.1%)**	**4,828 (98.9%)**

* Excluding those for export, including those cancelled or withdrawn

In terms of manufacturing, import marketing approval and notification status for 2020, the manufacturing items have more approval items than notification items by 2,163 items(46.8%); import items have more approval items than notification items by 108 items(40.2%).

Table 4 Marketing Approval and Notification Status by Manufacturing, Import in 2020

(Unit: number of items)

Classification	Total	Manufacturing	Import
Approval	**3,576**	3,388 (73.4%)	188 (70.1%)
Notification	**1,305**	1,225 (26.6%)	80 (29.9%)
Total	**4,881**	**4,613 (100%)**	**268 (100%)**

* Excluding those for export, including those cancelled or withdrawn

When looking at the present status of manufacturing, import marketing approval and notification by regional office in 2020 only, out of total 4,828 items, approval items were 3,523 items, of which manufacturing items were 3,342 items(94.9%), taking most part. In details, among the manufacturing items, approval items were more than notification items by 2,117 items(46.4%) and among import items, approval items were more than notification items by 108 items(70.1%).

Table 5 Manufacturing, Import Marketing Approval and Notification Status by Processing Institution in 2020

(Unit: number of items)

Manufacturing (4,613 items)		Import (268 items)	
Approval (3,388)	HQ (46)	Approval (188)	HQ (7)
	Regional office (3,342)		Regional office (181)
Notification (1,225)	Regional office (1,225)	Notification (80)	Regional office (80)

* Excluding those for export, including those cancelled or withdrawn

According to the present status of manufacturing, import marketing approval and notification by Gyeongin regional office processed the most items with 2,380 items(49.3%), followed by Seoul regional office with 813 items(16.8%). Processing volume of Gyeongin regional office and Seoul regional office combined was 3,193 items, corresponding to 66.1% of the total.

Table 6 Manufacturing, Import Marketing Approval and Notification by Regional Office of Food and Drug Safety in 2020

(Unit: number of items)

Classification		Approval	Notification	Total
Regional Office	Gyeongin	1,832 (37.9%)	548 (11.4%)	**2,380** **(49.3%)**
	Seoul	604 (12.5%)	209 (4.3%)	**813** **(16.8%)**
	Daejeon	444 (9.2%)	348 (7.2%)	**792** **(16.4%)**
	Daegu	210 (4.3%)	99 (2.1%)	**309** **(6.4%)**
	Busan	204 (4.2%)	33 (0.7%)	**237** **(4.9%)**
	Gwangju	229 (4.7%)	68 (1.4%)	**297** **(6.2%)**
Total		**3,523** **(73.0%)**	**1,305** **(27.0%)**	**4,828** **(100.0%)**

* Excluding those for export, including those cancelled or withdrawn

1.3. Manufacturing, Import Marketing Approval and Notification by Classification Code

In terms of marketing approval and notification status for 2020 by classification code, filtering respirator(33.8%), anti-droplet mask(24.9%), external disinfectant (15.5%), menstrual pad(8.9%), surgical mask(8.4%), toothpaste(4.2%), adhesive bandage(2.6%), mouthwash(0.3%) are in the order named.

Table 7 Approval and Notification by Classification Code in 2020

(Unit: number of items)

Code / Total	Filtering Respirator [32200]	Anti-droplet Mask [32300]	External Disinfectant [46000]	Menstrual Pad [31100]	Surgical Mask [32100]	Toothpaste [41400]	Adhesive Bandage [33800]	Mouthwash [41100]	Others
4,881	1,651 (33.8%)	1,214 (24.9%)	755 (15.5%)	436 (8.9%)	408 (8.4%)	204 (4.2%)	128 (2.6%)	17 (0.3%)	68 (1.4%)

* Excluding those for export, including those cancelled or withdrawn

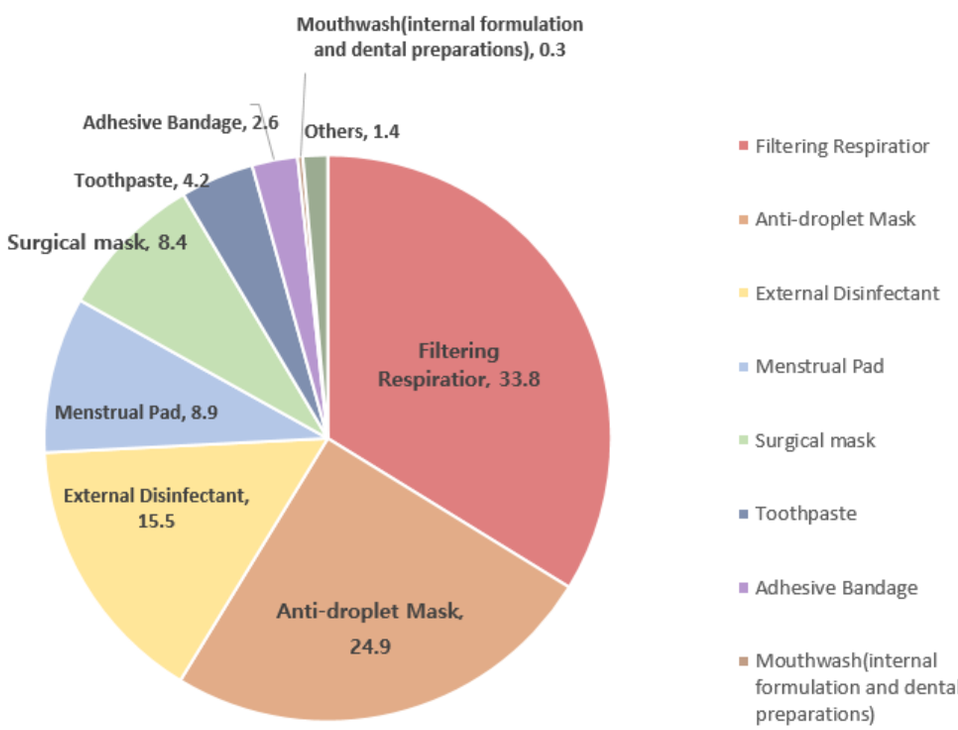

Fig. 2 Marketing Approval and Notification Distribution by Classification Code in 2020

When comparing Marketing Approval and Notification by classification code in 2020 with those in 2019, filtering respirator was 33.8%(1,651 items) for consecutive 2 years, taking the highest percentage following 2019. In particular, the marketing approval and notifications of 3 types of quasi-drug masks (filtering respirator, surgical mask, anti-droplet mask) including filtering respirator were 3,273 items, taking 67.1%.

In addition, anti-droplet mask, which was newly designated and announced as quasi-drug in 2020 was 24.9%(1,214 items), followed by external disinfectants of 15.5%(755 items). Menstrual pad, taking the highest percentage in 2019, was 8.9%, with decrease of 55 items of marketing approval and notification, compared to 2019. In terms of classification code, the number of marketing approval and notification item decreased.

Table 8 Marketing Approval and Notification by Classification Code in 2020 (2019-2020)

(Unit: number of items)

Year	Filtering Respirator [32200]	Anti-droplet Mask [32300]	External Disinfectant [46000]	Menstrua Pad [31100]	Surgical Mask [32100]	Tooth paste [41400]	Adhesive Bandage [33800]	Mouth wash [41100]	Others	Total
2020	**1,651 (33.8%)**	**1,214 (24.9%)**	**755 (15.5%)**	**436 (8.9%)**	**408 (8.4%)**	**204 (4.2%)**	**128 (2.6%)**	**17 (0.3%)**	**68 (1.4%)**	**4,881**
2019	439 (32.0%)	-	26 (1.9%)	491 (35.8%)	22 (1.6%)	152 (11.1%)	105 (7.7%)	12 (0.9%)	123 (9.0%)	1,370

* Excluding those for export, including those cancelled or withdrawn

Table 9 Detailed Status of Marketing Approval and Notification by Classification Code in 2020

Classification	Classification Code		Number of Items
Item A*	3110	Menstrual Pad	436
	3120	Menstrual Tampon	9
	3130	Menstrual Cup	5
	3210	Surgical Mask	408
	3220	Filtering Respirator	1,651
	3230	Anti-droplet Mask	1,214
	3330	Elastic Bandage	7
	3350	Tubular Compression Bandage (Stokinet)	1
	3360	Gauze	9
	3370	Absorbent Cotton	7
	3380	Adhesive Bandage	128
	Subtotal		**3,875**
Item B**	4110	Mouthwash (internal formulation and dental preparations)	17
	4140	Toothpaste	204
	4320	Repellent	6
	4400	Contact Lens Care Product	3
	4600	External Disinfectant	755
	4713	Spray Patch	1
	4721	Low-content Vitamin and Mineral Agent	8
	4722	Nutrients, Tonic and Alternatives (internal liquid formulation only)	1
	4840	Teeth Whitening Solution	1
	4850	Preparation for cleaning and disinfecting denture (false teeth), dental braces and other removable oral device	2
	Subtotal		**998**
Similar to Item A and B	3500	Other Similar Product	7
	4920	Portable product containing air composition or oxygen manufactured to be breathed in by person	1
	Subtotal		**8**
Total			**4,881**

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

Ministry of Food and Drug Safety

02

Detailed Status of Quasi-Drug Approval in 2020

02

Detailed Status of Quasi-Drug Approval in 2020

Quasi-drug is 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.

Out of marketing approval of 3,576 items in 2020, Item A were 3,479 items(97.3%), Item B were 89 items(2.5%), similar to Item A and B were 8 items(0.2%), indicating that items falling under Item A account for the majority.

Among the quasi-drugs approved in 2020, the targets of safety and effectiveness examination were 53 items, which indicates increase of 25 items(89.3%) compared to 28 items in 2019. Among these, 46 items(86.8%) were manufacturing items.

When analyzing 53 items subject to safety and effectiveness examination approved in 202 by item, Item A were 42 items(4 items of menstrual cup, 1 item of surgical mask, 16 items of filtering respirator, 21 items of anti-droplet mask), Item B were 10 items(3 items of mouthwash, 7 items of toothpaste), similar to Item A and B was 1 item (1 item of portable air and oxygen agent).

Table 10-1 Marketing Approval Status by Items of Quasi-Drug (2019-2020)

(Unit: number of items)

Year	Total	Item A	Item B	Article C**	Similar to Item A and B
2020	**3,576**	**3,479 (97.3%)**	**89 (2.5%)**	**-**	**8 (0.2%)**
2019	742	672 (90.6%)	60 (8.1%)	-	10 (1.3%)

* Excluding those for export, including those cancelled or withdrawn

** Domestic insecticide among Item B and C, Subparagraph 7 of Article 2 of 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 (2019-2020)

(Unit: number of items)

Classification	Total	Manufacturing	Import
2020	**53**	**46(86.8%)**	**7(13.2%)**
2019	28	20(71.4%)	8(28.6%)

* Excluding those for export, including those cancelled or withdrawn

Table 10-3 Status of Marketing Approval Subject to Safety and Effectiveness Examination by Item in 2020

Classification	Types	Item Classification	Number of Approval Items
1	Item A	Menstrual Cup	4
		Surgical Mask	1
		Filtering Respirator	16
		Anti-droplet Mask	21
2	Item B	Mouthwash	3
		Toothpaste	7
3	Similar to Item A and B	Portable Air and Oxygen Agent	1

2.1. Item A Quasi-Drug Approval Status

Item A quasi-drugs are the products that falls on textile, rubber products or similar to this used for purpose of treating, alleviating, treating or preventing the disease of humans or animals, including sanitary pad, mask, and gauze, etc.

In terms of Marketing Approval Status of Item A Quasi-Drug in 2020, filtering respirator was 1,651 items(42.6%), followed by 1,214 items of anti-droplet mask(34.9%), 408 items of surgical mask(11.7%) and 114 items of menstrual pad(3.3%) in the order named.

Table 11 Marketing Approval Status of Item A Quasi-Drug in 2020

By Items		Marketing Approval (number)
Menstrual Hygiene Management Product	Menstrual Pad	114(3.3%)
	Menstrual Tampon	0(0.0%)
	Menstrual Cup	5(0.1%)
Mask	Surgical Mask	408(11.7%)
	Filtering Respirator	1,651(47.5%)
	Anti-droplet Mask	1,214(34.9%)
Elastic Bandage		5(0.1%)
Tubular Compression Bandage (Stokinet)		0(0.0%)
Gauze		2(0.1%)
Absorbent Cotton		0(0.0%)
Adhesive Bandage		80(2.3%)
Total		**3,479**

1) Menstrual Hygiene Management Product

Menstrual hygiene management products are designated to include menstrual pad, menstrual tampon, menstrual cup. Among 119 items approved in 2020, menstrual pads were 114 items and menstrual cup were 5 items.

Among them, the items approved as the targets subject to safety and effectiveness examination were 4 items of menstrual cup, and items not subject to such examination were 114 items of menstrual pad and 1 item of menstrual cup.

Among the menstrual hygiene management product, classification of menstrual cup examination, the approval items subject to safety and effectiveness examination were new materials, and there were 3 items of manufacturing, 1 item of import.

Table 12 Status of Marketing Approval Subject to Safety and Effectiveness Examination of Menstrual Hygiene Management Product in 2020

No.	Mfg./ Import	Product	Company	Date of Approval	Classification Code	Remarks
1	Mfg.	비움컵엠 생리컵	주식회사조은정밀	2020-05-14	Menstrual Cup [31300]	New material
2	Import	클레리컵(소형, 중형)	디알스킨(주)	2020-06-09	Menstrual Cup [31300]	New material
3	Mfg.	바디앤컵제이일(중형, 소형)	(주)진경산업	2020-03-15	Menstrual Cup [31300]	New material
4	Mfg.	닉스컵(대형, 소형)	한국고무주식회사	2020-07-30	Menstrual Cup [31300]	New material

* Approved information of each products(efficacy, effect, direction for use, dosage and cautions for use) can be found at National Medicine Safety(http://nedrug.mfds.go.kr)

2) Mask

3 types of quasi-drug mask were designated and in 2020, 3,273 items(filtering respirator 1,651 items, surgical mask 408 items, anti-droplet mask 1,214 items) obtained marketing approval.

Among them, the approval items subject to safety and effectiveness examination were 38 items(filtering respirator 16 items, surgical mask 1 item, anti-droplet mask 21 items), and those not subject to such examination were 3,235 items (filtering respirator 1,635 items, surgical mask 407 items, anti-droplet mask 1,193 items).

Table 13 Status of Marketing Approval Subject to Safety and Effectiveness Examination of Mask in 2020

No.	Mfg./ Import	Product	Company	Date of Approval	Classification Code	Remarks
1	Mfg.	르에어황사마스크(KF80)(대형)(흰색)	(주)화진산업	2020-04-01	Filtering Respirator [32200]	New material
2	Mfg.	웰킵스미세먼지마스크KF80(중형, 소형)	(주)피앤티디	2020-04-08	Filtering Respirator [32200]	New material
3	Mfg.	웰킵스미세먼지마스크(KF80)(대형)	(주)피앤티디	2020-04-08	Filtering Respirator [32200]	New material
4	Mfg.	뉴매일편한보건용마스크(KF80)(대형)	마스크상사	2020-04-08	Filtering Respirator [32200]	New material
5	Mfg.	네퓨어식스황사마스크(KF80)	(주)파인텍	2020-04-09	Filtering Respirator [32200]	New material
6	Mfg.	에버그린에스엠에스보건용마스크(KF80)	(주)에버그린	2020-04-10	Filtering Respirator [32200]	New material
7	Mfg.	국제메디황사마스크(KF80)(대형, 소형)	국제약품(주)	2020-04-10	Filtering Respirator [32200]	New material
8	Mfg.	숨프리KF80황사마스크(KF80)(대형)	디스산업(주)	2020-04-13	Filtering Respirator [32200]	New material

No.	Mfg./ Import	Product	Company	Date of Approval	Classification Code	Remarks
9	Mfg.	가드맨안심황사마스크(KF80)(대형)	(주)다인누리	2020-04-13	Filtering Respirator [32200]	New material
10	Mfg.	닥터퓨리뉴에스황사마스크(KF80)(대형)	(주)케이엠	2020-04-13	Filtering Respirator [32200]	New material
11	Mfg.	닥터퓨리뉴에스황사마스크(KF80)(소형)	(주)케이엠	2020-04-13	Filtering Respirator [32200]	New material
12	Mfg.	블루본투디(KF80)(대형,소형)	(주)블루인더스	2020-04-14	Filtering Respirator [32200]	New material
13	Mfg.	블루본쓰리디(KF80)(대형, 소형)	(주)블루인더스	2020-04-16	Filtering Respirator [32200]	New material
14	Mfg.	엠씨미소황사마스크(KF80)(대형)	(주)엠씨	2020-05-29	Filtering Respirator [32200]	New material
15	Mfg.	프리비말마스크(KF-AD)	(주)파인텍	2020-06-01	Anti-droplet Mask [32300]	New efficacy
16	Mfg.	건영사각마스크(KF-AD)(대형)(흰색)	(유)건영크린텍	2020-06-01	Anti-droplet Mask [32300]	New efficacy
17	Mfg.	알파비말마스크(KF-AD)	(주)파인텍	2020-06-01	Anti-droplet Mask [32300]	New efficacy
18	Mfg.	웰킵스언택트마스크(KF-AD)(대형, 소형)	(주)피앤티디	2020-06-01	Anti-droplet Mask [32300]	New efficacy
19	Mfg.	건영3단마스크(KF-AD)(대형)(흰색)	(유)건영크린텍	2020-06-01	Anti-droplet Mask [32300]	New efficacy
20	Mfg.	케이엠옴니맥스마스크(KF-AD)	(주)케이엠	2020-06-02	Anti-droplet Mask [32300]	New efficacy
21	Mfg.	네퓨어비말에스마스크(KF-AD)	(주)파인텍	2020-06-02	Anti-droplet Mask [32300]	New efficacy
22	Mfg.	닥터퓨리뉴케어건강마스크(KF-AD)	(주)케이엠	2020-06-02	Anti-droplet Mask [32300]	New efficacy

No.	Mfg./ Import	Product	Company	Date of Approval	Classification Code	Remarks
23	Mfg.	케이엠옴니프로마스크 (KF-AD)	(주)케이엠	2020-06-02	Anti-droplet Mask [32300]	New efficacy
24	Mfg.	크린웰실드비말마스크 (KF-AD)(대형, 중형)	(주)크린웰	2020-06-09	Anti-droplet Mask [32300]	New efficacy
25	Mfg.	케이엠덴탈에스마스크	(주)케이엠	2020-06-12	Surgical Mask [32100]	New material
26	Mfg.	휴안청프레시70비말차단 마스크(KF-AD)(대형,중형,소형)	(주)디엠개발	2020-06-25	Anti-droplet Mask [32300]	New material
27	Mfg.	우리가족마스크(KF-AD)	웰케어	2020-06-29	Anti-droplet Mask [32300]	New material
28	Mfg.	퓨리케어마스크(KF-AD)	웰케어	2020-06-29	Anti-droplet Mask [32300]	New material
29	Mfg.	라이프가드마스크(KF-AD) (대형, 중형, 소형)	웰케어	2020-06-29	Anti-droplet Mask [3230]	New material
30	Mfg.	자연마음마스크(KF-AD)	웰케어	2020-07-06	Anti-droplet Mask [3230]	New material
31	Mfg.	닥터퓨리뉴케어울트라라이트 건강마스크(KF-AD)	(주)케이엠	2020-07-16	Anti-droplet Mask [3230]	New material
32	Mfg.	더시원한블루마스크평면형 (KF-AD)(백색)(대형)	(주)블루인더스	2020-07-16	Anti-droplet Mask [3230]	New efficacy
33	Mfg.	닥터퓨리뉴케어울트라라이트 입체마스크(KF-AD)	(주)케이엠	2020-07-16	Anti-droplet Mask [3230]	New material
34	Mfg.	데일리입체마스크(KF-AD)	(주)케이엠	2020-07-21	Anti-droplet Mask [3230]	New material
35	Mfg.	네오비말차단용마스크 (KF-AD)(대형, 소형)	주식회사 네오메드	2020-09-04	Anti-droplet Mask [3230]	New material
36	Mfg.	에어워셔베이직황사마스크 알파(KF80)	(주)파인텍	2020-04-10	Filtering Respirator [3220]	New material ※withdrawn (as of May, 2021)

No.	Mfg./ Import	Product	Company	Date of Approval	Classification Code	Remarks
37	Mfg.	웰클린숨편한비말차단용 마스크(KF-AD)(대형)(흰색)	주식회사 바이오플러스	2020-10-19	Anti-droplet Mask [3230]	New material ※withdrawn (as of May, 2021)
38	Import	블랑디오마스크대형(KF94)	에스제이 사이언스	2020-11-02	Filtering Respirator [3220]	New efficacy

* Approved information of each products(efficacy, effect, direction for use, dosage and cautions for use) can be found at National Medicine Safety(http://nedrug.mfds.go.kr)

2.2. Item B Quasi-Drug Approval Status

Item B quasi-drugs means non-appliance, non-machinery 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 Marketing Approval Status of Item B Quasi-Drug in 2020, external disinfectants were highest with 52 items(58.4%), followed by toothpaste 28 items(31.5%) and mouthwash 6 items(6.7%).

Table 14 Marketing Approval Status of Item B Quasi-Drug in 2020

By Items		Marketing Approval (number)
Preventive Oral Care Product	Mouthwash(internal formulation and dental preparations)	6(6.7%)
	Toothpaste	28(31.5%)
Repellent		0(0.0%)
Contact Lens Care Product		0(0.0%)
External Disinfectant		52(58.4%)
Teeth Whitening Solution		1(1.1%)
Spray Patch		0(0.0%)
Low-content Vitamin and Mineral Agent		0(0.0%)
Nutrients, Tonic and Alternatives(internal liquid formulation only)		0(0.0%)
Preparation for cleaning and disinfecting denture (false teeth), dental braces and other removable oral device		2(2.2%)
Total		**89**

1) Preventive Oral Care Product

Preventive oral care product of 34 items(mouthwash(internal formulation and dental preparations) of 6 items), toothpaste of 28 items obtained marketing approval.

Among them, 10 items(mouthwash 3 items, toothpaste 7 items) were approval items subject to safety and effectiveness examination, and 24 items(mouthwash 3 items, toothpaste 21 items) were approval items not subject to safety and effectiveness examination.

Classification of approval items subject to safety and effectiveness examination among the approval items of preventive oral care product includes complex with contents increase and decrease and complex with new compositions.

Table 15 Status of Marketing Approval Subject to Safety and Effectiveness Examination of Preventive Oral Care Product in 2020

No.	Mfg./ Import	Product	Company	Date of Approval	Classification Code	Remarks
1	Mfg.	1.메디안아쿠아마우스워시액, 2.메디안구취과학프리징쿨민트 마우스워시액	(주)국보싸이언스	2020-04-29	Mouthwash [4110]	Complex with new composition
2	Mfg.	1.플레시아후레쉬마우스워시액 등 2품목	주)국보싸이언스	2020-09-07	Mouthwash [4110]	Complex with new composition
3	Import	1.롱스핀엑스마우스워시 (페퍼민트향) (염화세틸피리디늄) 등 2품목	(주)엔터팜	2020-06-17	Mouthwash [4110]	Single agent
4	Mfg.	1.2080닥터크리닉랩충치케어, 2.2080닥터크리닉충치치약	애경산업(주)	2020-09-21	Toothpaste [4140]	Complex with contents increase and decrease
5	Mfg.	1.2080닥터크리닉랩치석케어, 2.2080닥터크리닉치석치약	애경산업(주)	2020-09-21	Toothpaste [4140]	Complex with contents increase and decrease
6	Mfg.	티블렛케어고체치약	(주)성원제약	2020-06-01	Toothpaste [4140]	Complex with contents increase and decrease

No.	Mfg./ Import	Product	Company	Date of Approval	Classification Code	Remarks
7	Import	콜게이트센시티브프로릴리프화이트	(주)우삼코리아	2020-01-28	Toothpaste [4140]	Complex with contents increase and decrease
8	Import	콜게이트센시티브프로릴리프화이트	(주)우삼코리아	2020-02-06	Toothpaste [4140]	Complex with contents increase and decrease
9	Import	콜게이트토탈차콜디프클린	(주)우삼코리아	2020-04-03	Toothpaste [4140]	Complex with contents increase and decrease
10	Import	콜게이트토탈차콜디프클린	(주)우삼코리아	2020-06-02	Toothpaste [4140]	Complex with contents increase and decrease

* Approved information of each products(efficacy, effect, direction for use, dosage and cautions for use) can be found at National Medicine Safety(http://nedrug.mfds.go.kr)

2) Mosquito and Mite Repellent used for Health

There were 6 new items of mosquito and mite repellents in 2020, but the items were notification items(items satisfying the standard manufacturing criteria) and no approval items.

It is considered as the phenomenon that occurred as the scope of target for safety and effectiveness examination of mosquito and mite was expanded(July 31, 2019).

3) External Disinfectant

External disinfectant, containing hydrogen peroxide, isopropyl alcohol, benzalkoniumchloride, cresol or ethanol directly working on human body, has been designated as quasi-drug.

As external disinfectant, new items of marketing approval and notification were 765 items in 2020, and among them, 713 items were for notification and 52 items were for marketing approval . In addition, 52 items for marketing approval were all not subject to safety and effectiveness examination.

2.3. Approval Status of Quasi-Drugs Similar to Item A and B

Quasi-drug similar to Item A and B were 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 use for surgical treatment for the purpose of infection prevention ▲wet tissue for mouth cleaning ▲items used to temporarily adjusting the color of teeth by applying on the tooth surface ▲portable product containing air composition or oxygen manufactured to be breathed in by person ▲items similar to each item in subparagraph 1.

For reference, the items used for sanitization of bleeding right after childbirth and lochia(vaginal discharge after childbirth) were additionally designated(Amended on Sep. 30, 2019, Implemented on Oct. 1, 2021).

In terms of Approval Status of quasi-drug similar to Item A and B in 2020, 1 item was approved as the portable product containing air composition or oxygen manufactured to be breathed in by person, which was item subject to safety and effectiveness examination.

Table 16 Marketing Approval Status of Quasi-Drug Similar to Item A and B in 2020

By Items	Marketing Approval (number)
Non-adhesive items used to absorb exudate of the affected area	3(37.5%)
Sterilized items use for surgical treatment for the purpose of infection prevention	4(50.0%)
Portable product containing air composition or oxygen manufactured to be breathed in by person	1(12.5%)
Total	**8**

Table 17 Marketing Approval Status Subject to (Air, Oxygen Agent) Safety and Effectiveness Examination in 2020

No.	Mfg./ Import	Product	Company	Date of Approval	Classification Code	Remarks
1	Mfg.	지리휴대용에어	주식회사 하동바이탈러티에어	2020-09-14	Portable product containing air composition or oxygen manufactured to be breathed in by person [4920]	Air composition

* Approved information of each products(efficacy, effect, direction for use, dosage and cautions for use) can be found at National Medicine Safety(http://nedrug.mfds.go.kr)

03

Quasi-drugs Approval Trend

03 Quasi-drugs Approval Trend

3.1. Status of Change in Quasi-drug Approval

According to manufacturing, import marketing approval and notification status since 2017, menstrual pad, filtering respirator, toothpaste, adhesive bandage, external disinfectant, etc. have accounted for high percentage, and it seems attributable to the system improvement such as change or new addition of item classification according to revision of regulations.

Classification of hair colorant, the upper item of marketing approval in 2017, was changed from quasi-drug to functional cosmetics according to revision of 「Cosmetics Act」 (May 30, 2017). In addition, bath care product, anti-hair loss product and depilatory were changed to functional cosmetics.

The insecticide for quarantine, the upper item of marketing approval in 2018 was transferred to the 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 right after childbirth and lochia(vaginal discharge after childbirth) was additionally designated as a new quasi-drug in 2019, and the effective date is Oct. 1, 2021.

In 2020, there were 3,325 items of new marketing approval of mask(filtering respirator, surgical mask, anti-droplet mask) and external disinfectant which were

always used by consumers for prevention of infectious diseases due to continuation of COVID-19 pandemics. It took 93% of 3,576 items for the total marketing approval, recording very high percentage.

Table 18 Status of Upper Item(Classification Code) of Marketing Approval by Year(2017-2020)

No,	2017		2018		2019		2020	
	Item	No. of Items	Item	No. of Items	Item	No. of Items	Item	No. of Items
1	Hair colorant(inclusing bleaching and demineralising agents)* (4220)	617 (37.6%)	Menstrual Pad (3110)	590 (40.8%)	Menstrual Pad (3110)	491 (35.8%)	**Filtering Respirator (3220)**	**1,651 (46.2)**
2	Menstrual Pad (3110)	317 (19.3%)	Toothpaste (4140)	189 (13.1%)	Filtering Respirator (3220)	439 (32.0%)	**Anti-droplet Mask*** (3230)**	**1,214 (33.9)**
3	Toothpaste (4140)	149 (9.1%)	Insecticide for Quarantine** (5110)	164 (11.3%)	Toothpaste (4140)	152 (11.1%)	**Surgical Mask (3210)**	**408 (11.4)**
4	Adhesive Bandage (3380)	109 (6.6%)	Filtering Respirator (3220)	137 (9.5%)	Adhesive Bandage (3380)	105 (7.7%)	**Menstrual Pad (3110)**	**114 (3.2)**
5	Filtering Respirator (3220)	109 (6.6%)	Adhesive Bandage (3380)	97 (6.7%)	External Disinfectant (4600)	26 (1.9%)	**External Disinfectant (4600)**	**52 (1.5%)**
No. of Marketing Approval		1,640 (100%)		1,445 (100%)		1,370 (100%)		**3,576 (100%)**

* Hair colorant(inclusing bleaching and demineralising agents), changed to functional cosmetics according to Cosmetic Act as of May 30, 2017

** Insecticide for Quarantine, transferred to items under the Ministry of Environment as of Jan. 1, 2019

*** Anti-droplet Mask, additionally designated into the scope of quasi-drug as of June 1, 2020

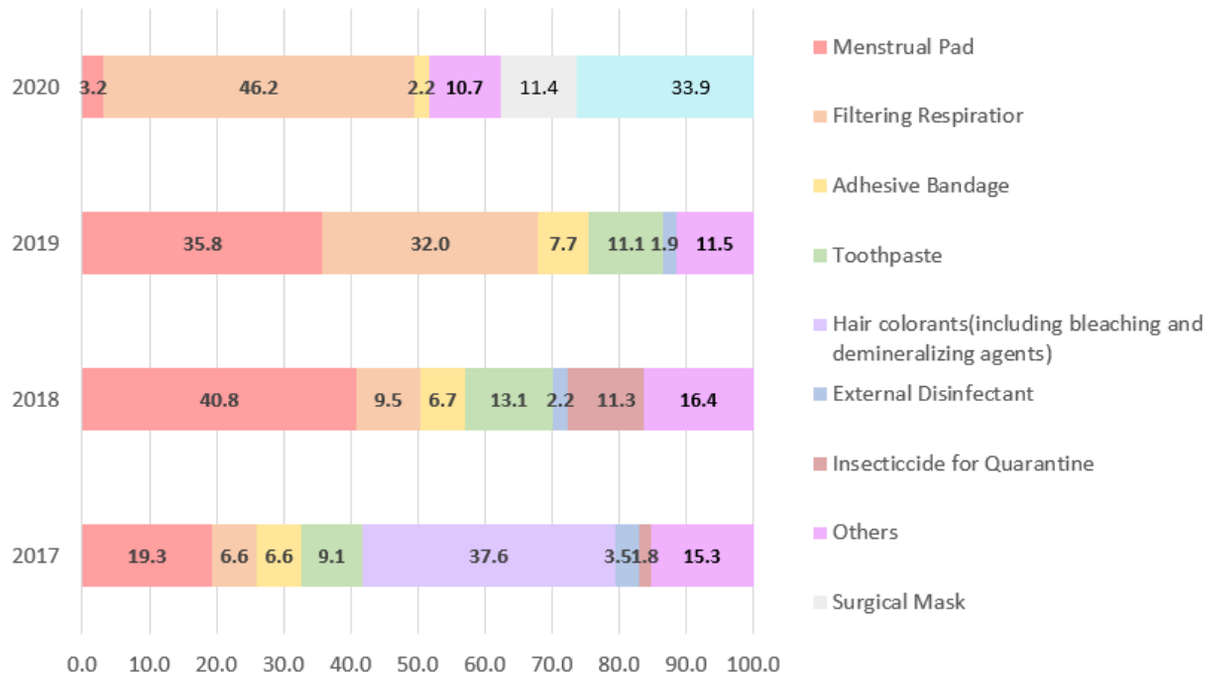

Fig. 3 Marketing Approval (Notification) Percentage by Quasi-Drug Classification Code by Year (2017-2020)

Besides, there have been continuous efforts to continue designation and expansion of scope of quasi-drugs. In this trend, as the number of users who use products similar to anti-smoking aids such as the product for inhalation after charging into electric device in addition to anti-smoking aid as quasi-drug according to strengthening of anti-smoking policy including cigarette price increase, the scope was expanded to the quasi-drug anti-smoking aid(not containing nicotine) for safety management of the relevant items in 2015.

In 2017, menstrual cup was newly added so that women can select various kinds of menstrual hygiene management product according to their life pattern for their health life.

In 2020, anti-droplet mask was newly added(June 1, 2020), which can be used by the consumers in daily life to block the droplets for prevention of infectious disease due to continuation of COVID-19 pandemic.

3.2 New Status of Quasi-Drugs in 2020

The first item approved as a quasi-drug in 2020 was the anti-droplet mask(used to prevent infection through droplet in daily live) which was designated into the scope of quasi-drug in June 2020. 1,214 items obtained marketing approval and among them 21 items were subject to safety and effectiveness examination.

Table 19 Marketing Approval Status Subject to Anti-Droplet Mask Safety and Effectiveness Examination

No.	Mfg./ Import	Product	Company	Date of Approval
1	Mfg.	프리비말마스크(KF-AD)	(주)파인텍	2020-06-01
2	Mfg.	건영사각마스크(KF-AD)(대형)(흰색)	(유)건영크린텍	2020-06-01
3	Mfg.	알파비말마스크(KF-AD)	(주)파인텍	2020-06-01
4	Mfg.	웰킵스언택트마스크(KF-AD)(대형, 소형)	(주)피앤티디	2020-06-01
5	Mfg.	건영3단마스크(KF-AD)(대형)(흰색)	(유)건영크린텍	2020-06-01
6	Mfg.	케이엠옴니맥스마스크(KF-AD)	(주)케이엠	2020-06-02
7	Mfg.	네퓨어비말에스마스크(KF-AD)	(주)파인텍	2020-06-02
8	Mfg.	닥터퓨리뉴케어건강마스크(KF-AD)	(주)케이엠	2020-06-02
9	Mfg.	케이엠옴니프로마스크(KF-AD)	(주)케이엠	2020-06-02
10	Mfg.	크린웰실드비말마스크(KF-AD)(대형,중형)	(주)크린웰	2020-06-09
11	Mfg.	휴안청프레시70비말차단마스크(KF-AD)(대형,중형,소형)	(주)디엠개발	2020-06-25
12	Mfg.	우리가족마스크(KF-AD)	웰케어	2020-06-29
13	Mfg.	퓨리케어마스크(KF-AD)	웰케어	2020-06-29
14	Mfg.	라이프가드마스크(KF-AD)(대형,중형,소형)	웰케어	2020-06-29
15	Mfg.	자연마음마스크(KF-AD)	웰케어	2020-07-06
16	Mfg.	닥터퓨리뉴케어울트라라이트건강마스크(KF-AD)	(주)케이엠	2020-07-16
17	Mfg.	더시원한블루마스크평면형(KF-AD)(백색)(대형)	(주)블루인더스	2020-07-16
18	Mfg.	닥터퓨리뉴케어울트라라이트입체마스크(KF-AD)	(주)케이엠	2020-07-16
19	Mfg.	데일리입체마스크(KF-AD)	(주)케이엠	2020-07-21
20	Mfg.	네오비말차단용마스크(KF-AD)(대형, 소형)	주식회사 네오메드	2020-09-04
21	Mfg.	웰클린숨편한비말차단용마스크(KF-AD)(대형)(흰색)	주식회사바이오플러스	2020-10-19 ※withdrawn (as of May, 2021)

Appendix Departments Handling Quasi-Drug Complaints

Table 20 Status of Departments Handling Complaints of Quasi-drugs (As of May, 2021)

<table>
<tr><th>Classification</th><th>Department</th><th>Detailed Petition Service</th></tr>
<tr><td colspan="2">Director for Novel Products Approval</td><td>Quasi-drug manufacturing, import marketing approval (including change)
• tems subject to safety and effectiveness examination only</td></tr>
<tr><td>Biopharmaceuticals and Herbal Medicine Bureau</td><td>Quasi-drugs Policy Dept.</td><td>Quasi-drug GMP evaluation</td></tr>
<tr><td>National institute of Food and Drug Safety Evaluation</td><td>Biopharmaceuticals and Herbal Medicine Evaluation Dept.

Cosmetics Evaluation Division</td><td>Quasi-drug
• Safety and effectiveness examination
• Review of quality data
• Preview</td></tr>
<tr><td>Seoul Regional Office of Food and Drug Safety</td><td>Pharmaceutical Safety Management Division</td><td rowspan="7">Quasi-drug manufacturing, import marketing approval and notification (including change)
• Limited to items not subject to safety and effectiveness examination

Quasi-drug permission for manufacturing business (including change)</td></tr>
<tr><td>Gyeongin Regional Office of Food and Drug Safety</td><td rowspan="6">Medical Product Safety Division</td></tr>
<tr><td>Daejeon Regional Office of Food and Drug Safety</td></tr>
<tr><td>Busan Regional Office of Food and Drug Safety</td></tr>
<tr><td>Daegu Regional Office of Food and Drug Safety</td></tr>
<tr><td>Gwangju Regional Office of Food and Drug Safety</td></tr>
</table>

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2020
Quasi-Drug Approval Report

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