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2021 Drug Approval Report

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Ministry of Food and Drug Safety

Director for Approval Management

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General Status of 2021 Drug Approval (Notification)

1. General Status of 2021 Drug Approval (Notification)

The purpose of the 2021 Drug Approval Report is to organize, analyze, and share the status of approval and notification of all drugs in a multi-faceted manner in line with the 2020 Drug Approval Report for establishing and executing relevant policies, systematizing and streamlining approval and notification tasks, and supporting product development.

1.1. General Status

In 2021, 2,270 drugs were approved and notified, including chemical drugs, biopharmaceuticals, and herbal (oriental) medicines. The status of the drug approval and notification in 2021 is shown in Table 1. The total number of items decreased by around 35.1% (1,226 items) compared to the previous year, and in particular, the number of approval and notification for manufacturing items decreased sharply by 36.8% (1,224 items). The decrease down to the level of 2018 seems to be from the limitation on the number of approved items for joint use of clinical trial (bioequivalence test) data introduced in July 2021.

Table 1. Status of Drug Approval and Notification (2018~2021)

(Unit: Number of items)

Year	Total	Approval	Notifica-tion	MFDS	Regional FDS	Manufac-tured	Imported	Drug product	Drug substance (excluding herbal substances)	Herbal substances	Drug product	
											Prescribed	OTC
2021	2,270	1,514 (66.7%)	756 (33.3%)	499 (22.0%)	1,771 (78.0%)	2,099 (92.5%)	171 (7.5%)	1,992 (87.7%)	83 (3.7%)	195 (8.6%)	1,542 (77.4%)	450 (22.6%)
		Excluding medicinal herbs (195)		Excluding medicinal herbs (195)		Excluding medicinal herbs (195)		Excluding medicinal herbs(%)				
		1,512 (72.9%)	563 (27.1%)	499 (24.0%)	1,576 (76.0%)	1,904 (91.8%)	171 (8.2%)	96.0%	4.0%			
2020	3,496	2,319 (66.3%)	1,177 (33.7%)	738 (21.1%)	2,758 (78.9%)	3,323 (95.1%)	173 (4.9%)	3,229 (92.4%)	69 (2.0%)	198 (5.7%)	2,525 (78.2%)	704 (21.8%)
		Excluding medicinal herbs (198)		Excluding medicinal herbs (198)		Excluding medicinal herbs (198)		Excluding medicinal herbs (%)				
		2,315 (70.2%)	983 (29.8%)	734 (22.3%)	2,564 (77.7%)	3,125 (94.8%)	173 (5.2%)	97.9%	2.1%			
2019	6,187	3,691 (59.7%)	2,496 (40.3%)	629 (10.2%)	5,558 (89.8%)	6,035 (97.5%)	152 (2.5%)	4,809 (77.7%)	71 (1.2%)	1,307 (21.1%)	4,139 (86.1%)	670 (13.9%)
		Excluding medicinal herbs (1307)		Excluding medicinal herbs (1307)		Excluding medicinal herbs (1307)		Excluding medicinal herbs(%)				
		3,684 (75.5%)	1,196 (24.5%)	622 (12.7%)	4,258 (87.3%)	4,728 (96.9%)	152 (3.1%)	98.5%	1.5%			
2018	2,482	1,379 (55.6%)	1,103 (44.4%)	397 (16.0%)	2,085 (84.0%)	2,360 (95.1%)	122 (4.9%)	2,046 (82.4%)	75 (3.0%)	361 (14.6%)	1,514 (74.0%)	532 (26.0%)
		Excluding medicinal herbs (361)		Excluding medicinal herbs (361)		Excluding medicinal herbs (361)		Excluding medicinal herbs(%)				
		1,378 (65.0%)	743 (35.0%)	396 (18.7%)	1,725 (81.3%)	1,999 (94.2%)	122 (5.8%)	96.5%	3.5%			

* Excluding drugs for export (83 items), including revoked·withdrawn items and medicinal herbs.

Approval accounted for 66.7% (1,514 items), and notification took up 33.3% (756 items) of the total (2,270 items). According to the analysis by institutions, the MFDS handled 22.0% (499 items) while the Regional FDS processed 78.0% (1,771 items). The number of items approved and notified in 2021 has decreased compared to 2020.

Domestically manufactured and marketed items occupied 92.5% (2,099 items), whereas imported items accounted for 7.5% (171 items).

Drug products made up 87.7% (1,992 items), drug substances 3.7% (83 items), and medicinal herbs 8.6% (195 items). This analysis shows a decrease in the number of drug products, an increase for drug substances, and a similar number for medicinal herbs.

The number of drug products (96.0%) was significantly higher than drug substances (4.0%) when excluding medicinal herbs. Among drug products, 77.4% were ETC drugs (1,542 items), and 22.6% were OTC drugs (450 items).

Domestically manufactured and marketed items accounted for the majority of the approved and notified drug products in 2021, as they did in 2020. Though the number of approval and notification for domestically manufactured and marketed items (excluding medicinal herbs) increased significantly in 2019 (4,728 items) compared to 2018 (1,999 items), it decreased by around 33.9% in 2020 (3,125 items), and by 39.1% in 2021 (1904 items) compared to the previous years. This is presumed to be due to the restriction on the number of items that use joint clinical (bioequivalent) data among the consigned items.

For notified items (excluding medicinal herbs), the number has not shown significant changes for a while since 2011 (753 items). However, it increased by 1.7 times (453 items) in 2019, then decreased by 17.9% (213 items) in 2020, and continued to decrease by 43.0% in 2021 (420 items).

The number of medicinal herbs that were approved or notified was 195 items in 2021, similar to that of 2020 (198 items).

Table 2-1. Status of the Number of Drug Approval/Notification by Year (excluding medicinal herbs)

(Unit: Number of items)

Category	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
Approval	853	831	1,423	1,811	2,110	2,030	1,306	1,378	3,684	2,315	1,512
(Year-on-year increase, %)	-2.5%	71.2%	27.3%	16.6%	-3.8%	-35.7%	5.5%	167.3%	-37.2%	-34.7%	
Notification	753	687	787	1,118	904	815	798	743	1,196	983	563
(Year-on-year increase, %)	-8.7%	14.6%	42.1%	-19.1%	-9.8%	-2.1%	-6.9%	61.0%	-17.8%	-42.7%	
Total	1,606	1,518	2,210	2,929	3,014	2,845	2,104	2,121	4,880	3,298	2,075
(Year-on-year increase, %)	-5.4%	45.6%	32.5%	2.9%	-5.6%	-26.0%	8.1%	130.1%	-32.4%	-37.1%	

* Excluding drugs for export and medicinal herbs, including revoked·withdrawn items

Table 2-2. Number of Drug Approvals/Notifications by Year (including medicinal herbs)

(Unit: Number of items)

Category	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
Approval	853	835	1,423	1,811	2,110	2,036	1,315	1,379	3,691	2,319	1,514
(Year-on-year increase, %)	-2.1%	70.4%	47.3%	16.6%	-3.5%	-35.4%	4.9%	167.7%	-37.2%	-34.7%	
Notification	7,269	3,898	973	1,296	2,813	1,792	1,209	1,103	2,496	1,177	756
(Year-on-year increase, %)	-46.3%	-75.0%	33.2%	117.1%	-36.3%	-32.5%	-8.8%	126.3%	-52.8%	-35.8%	
Total	8,122	4,733	2,396	3,107	4,923	3,828	2,524	2,482	6,187	3,496	2,270
(Year-on-year increase, %)	-41.7%	-49.4%	29.7%	58.4%	-22.2%	-34.1%	-1.7%	149.3%	-43.5%	-35.1%	

* Excluding drugs for export, including revoked·withdrawn items

Table 2-3. Number of Medicinal Herb Notifications by Year

(Unit: Number of items)

Category	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
Medicinal herb	6,516	3,211	186	178	1,909	983	420	361	1,307	198	195
(Year-on-year increase, %)	-50.7%	-94.2%	-4.3%	972.5%	-48.5%	-57.3%	-14.0%	262.0%	-85.2%	-1.5%	

* Excluding drugs for export, including revoked·withdrawn items

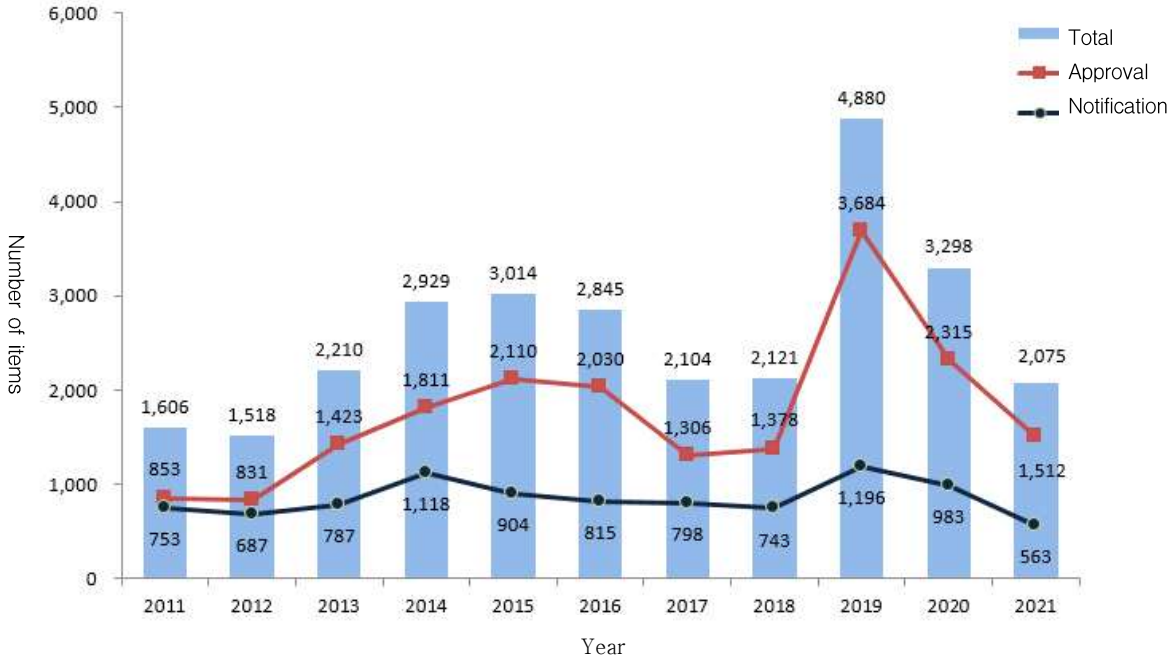

Figure 1-1. Number of Approved and Notified Drugs (2011~2021)
(excluding medicinal herbs)

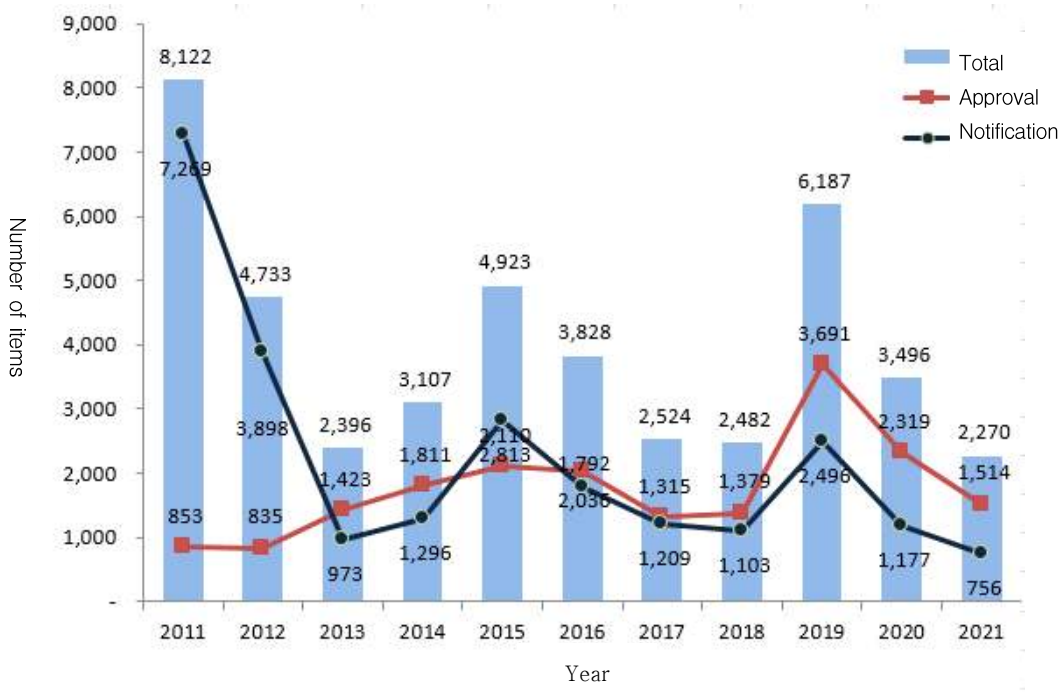

Figure 1-2. Number of Approved and Notified Drugs (2011~2021)
(including medicinal herbs)

A detailed analysis of the drug approval and notification in 2021 shows that the Regional FDS approved 1,013 items (67.0%) out of the total items approved (1,512 items), which is approximately 2.0 times the number of items approved by the MFDS (499 items, 33.0%). (See Table 3-1). In addition, 998 (98.5%) out of 1,013 items approved by the Regional FDS were manufactured and marketed products (see Table 3-2).

This indicates that the number of generic drugs assigned to the Regional FDS for approval is relatively higher than the number of drugs that require data submission assigned to the MFDS, and that these drugs are domestically manufactured.

Table 3-1. Drug Approval and Notification Status by Institution in 2021

(Unit: Number of items)

Category	Total	MFDS	Regional MFDS
Approval	1,512 (100%)	499 (33.0%)	1,013 (67.0%)
Notification	563	0	563
Medicinal herbs	195	0	195
Total	2,270 (100%)	499 (22.0%)	1,771(78.0%)

* Excluding drugs for export (83 items), including revoked·withdrawn items, including medicinal herbs

Table 3-2. Overview of Drug Approval and Notification Status in 2021

(Unit: Number of items)

Domestically manufactured (1,904 items)				Imported (171 items)			
Drug product (1,889) 99.2%	ETC (1,446) 76.5%	Approval (1,366)	MFDS (368)	**Drug product (103)** 60.2%	ETC (96) 93.2%	Approval (94)	MFDS (79)
			Regional FDS (998)				Regional FDS (15)
		Notification (80)	Regional FDS (80)			Notification (1)	Regional FDS (1)
	OTC (443) 23.5%	Approval (29)	MFDS (29)		OTC (7) 6.8%	Approval (5)	MFDS (5)
		Notification (414)	Regional FDS (414)			Notification (2)	Regional FDS (2)
Drug substance (15) 0.8%		Approval (7)	MFDS (7)	**Drug substance (68)** 39.8%		Approval (11)	MFDS (11)
		Notification (8)	Regional FDS (8)			Notification (57)	Regional FDS (57)

* Excluding drugs for export (83 items), including revoked·withdrawn items, including medicinal herbs

According to the analysis of the approval · notification by the Regional FDS, the three regions that accounted for the majority (83.5%) of the total number were Gyeongin FDS, Daejeon FDS and Seoul FDS, with the rate of 39.9% (706 items), 29.6% (525 items) and 14.0% (248 items) respectively. For notification of medicinal herbs, the three regions that accounted for the majority of the total number were Daegu FDS, Daejeon FDS and Seoul FDS, with the rate of 41.0% (80 items), 25.6% (50 items) and 19.0% (37 items) respectively (see Table 4).

Table 4. Detailed Status of Drug Approval and Notification by Regional FDS in 2021

(Unit: Number of items)

Category		Approval	Notification	Medicinal herbs	Total
Regional FDS	Geyongin	473 (46.7%)	232 (41.2%)	1 (0.5%)	706 (39.9%)
	Seoul	123 (12.1%)	88 (15.6%)	37 (19.0%)	248 (14.0%)
	Daejeon	312 (30.8%)	1.063 (29.0%)	50 (25.6%)	525 (29.6%)
	Gwangju	46 (4.5%)	25 (4.4%)	16 (8.2%)	87 (4.9%)
	Daegu	22 (2.2%)	40 (7.1%)	80 (41.0%)	142 (8.0%)
	Busan	37 (3.7%(	15 (2.7%)	11 (5.6%)	63 (3.6%)
Total		1,013 (100%)	563 (100%)	195 (100%)	1,771 (100%)

* Excluding drugs for export (83 items), including revoked·withdrawn items, including medicinal herbs

According to the analysis of the approval · notification for manufactured and imported items, approved items took up a higher percentage than those that were notified for both types of items. For manufactured

products, there were 31.8% more items approved (66.9%) than notified (33.1%), and for imported products, there were approximately 28.6% more items approved (64.3%) than notified (35.7%) (see Table 5).

Table 5. Status of Manufactured and Imported Drugs in 2021

(Unit: Number of items)

Category	Total	Manufactured	Imported
Approval	1,514	1,404 (66.9%)	110 (64.3%)
Notification	756	695 (33.1%)	61 (35.7%)
Total	2,270	2,099 (100%)	171 (100%)

* Excluding drugs for export (83 items), including revoked·withdrawn items, including medicinal herbs

For drug products and substances, 75.0% (1,494 items) of drug products were approved, whereas 21.7% (18 items) of drug substances (excluding medicinal herbs) were approved and 78.3% (65 items) were notified (see Table 6).

Table 6. Detailed Status of Approval and Notification for Drug Products and Substances in 2021

(Unit: Number of items)

Category	Total	Drug products	Drug substances (including medicinal herb)	Drug substances (excluding medicinal herbs)
Approval	1,514	1,494 (75.0%)	20 (7.2%)	18 (21.7%)
Notification	756	498 (25.0%)	258 (92.8%)	65 (78.3%)
Total	2,270	1,992 (100%)	278 (100%)	83 (100%)

* Excluding drugs for export (83 items), including revoked·withdrawn items
* Drug substances that are subjects of DMF registration are excluded as they do not require separate approval or notification.

According to the analysis by the types of drug products (approved and notified items), chemical drugs accounted for the majority at 93.3% (1,859 items), herbal (oriental) medicine at 4.2% (83 items), biopharmaceuticals at 1.6% (32 items), and advanced Biological products occupied 0.9% (18 items) (see Table 7).

Table 7. Classification Status of Chemical Drugs, Biopharmaceuticals, Advanced Biological Products and Herbal (oriental) medicines in 2021

(Unit: Number of items)

Category	Total[1)]	Chemical drugs[2)]	Biopharma-ceuticals[3)]	Advanced Biological Products[4)]	Herbal (oriental) medicines[5)]
Drug products	1,992	1,859 (93.3%)	32 (1.6%)	18 (0.9%)	83 (4.2%)

1) Excluding drugs for export (83 items), including revoked·withdrawn items
2) Out of 1,859 items, 416 items were approved by the MFDS
3) All items were approved by the MFDS (excluding advanced Biological products)
4) All items were approved by the MFDS
5) Out of 83 items, 11 items were approved by the MFDS .

For approval and notification of drug products, 35 items (1.8%) were new drugs (including orphan drugs), 22 items (1.1%) were orphan drugs (excluding new drugs), 321 items (16.1%) were drugs that require data submission, and 1,614 items (81.0%) were generic drugs. This analysis showed that the generic drugs took up the highest percentage. Among drugs that require data submission, seven chemical drugs were certified as incrementally modified drugs by either using new composition, or changing the route of administration or compounding ratio, and two were certified as advanced biological products (see Table 8).

Table 8. Classification Status of Drug Products by Review Type in 2021

(Unit: Number of items)

Category	Type (Total)	New drugs		Orphan drugs	Drugs that require data submission		Others		
		New drugs	New orphan drugs	Orphan drugs	IMDs	Drugs that require data submission	Herbal medicines based on herbal medicine books	(MFDS)	(Regional FDS)
Drug products	Chemical drugs 1,859	22	-	15	7	280	-	92[4]	1,443[5]
	Biopharmaceuticals 32[6]	9	1	4	2	16	-	-	-
	Advanced biological products 18	-	2	3	-	13	-	-	-
	Herbal (oriental) medicines 83	1	-	-	-	3	6	1	72
Total	1,992[1] (100%)	32	3[3]	22 (1.1%)	9	312	6	93	1,515
		35[2] (1.8%)			321 (16.1%)		1,614 (81.0%)		

1) Excluding drugs for export (83 items), including revoked·withdrawn items

2) In 2021, there were 35 items that were approved as new drugs. Among those that were designated as new drugs through post-approval changes (either from the revocation or designation as orphan drugs) (3 items), only the new drugs that were newly approved in 2021 through post-approval changes were included (1 item)(see Table 15).

3) New drug ingredients that were designated as both orphan drugs and new drugs (designated through re-review).

4) Special dosage forms, generic narcotic drugs, items exempt from safety and efficacy evaluation, etc.

5) Items that are within the standard manufacturing criteria, generic items (excluding special dosage forms and narcotic drugs)

6) Excluding drugs for export and advanced biological products

Majority of the drug products that were approved by the MFDS were chemical drugs (416 items, 87.2%). It was found that the majority of the chemical drugs, herbal (oriental) medicines and advanced biological products that were approved were approved as manufactured products. However, for biopharmaceuticals (32 items, excluding advanced

biological products), it was found that the majority were approved as imported drugs (65.6%) (see Table 9).

Table 9. Detailed Status of Drug Product Approval (by the MFDS) in 2021

(Unit: Number of items)

Type	Total	Manufactured	Imported
Approved by the MFDS (drug products)	477	395	82
Chemical drugs	416 (87.2%)	356	60
Biophamaceuticals	32 (6.7%)	11	21
Advanced biological products	18 (3.8%)	15	3
Herbal (oriental) medicines	11 (2.3%)	11	0

* Excluding drugs for export, including revoked·withdrawn items

Among the approved drug products (1,992 items), 77.4% (1,542 items) were ETC drugs, which is approximately 3.4 times more than OTC drugs (22.6%, 450 items). Additionally, the number of approved drug products was about three times of those that were notified (see Table 10).

Table 10. Detailed Overview of Drug Product Approval Status in 2021

(Unit: Number of items)

Category	Total	ETC	OTC
Drug products	1,992 (100%)	1,542 (77.4%)	450 (22.6%)
Approval	1,494 (100%)	1,460 (97.7%)	34 (2.3%)
Notification	498 (100%)	82 (16.5%)	416 (83.5%)

* Excluding drugs for export (83 items) and medicinal herbs (195 items), including revoked·withdrawn items

Looking at the annual trends of the approval and notification in detail, the number of approved and notified items by drug type was similar in 2017 and 2018. However, in 2019 (6,187 items), the number increased by around 2.5 times the number in 2018. However, as the number of approved and notified ETC, OTC and medicinal herbs decreased from 2020, the number was returned to a similar number prior to 2019. This is presumed to be due to the recovery of the amount of generic drugs that surged from the reform of the drug price system.

Specifically, 1,542 ETC drugs, 450 OTC drugs and 195 medicinal herbs were approved in 2021, showing decrease in number by 38.9% (2,525 items), 36.1% (704 items) and 1.5% (198 items) compared to 2020, respectively. On the other hand, the number of approved and notified drug substances in 2021 was 83 items, showing increase in number by 20.3% compared to that of 2020 (69 items) (see Figure 2 and Table 11).

Table 11. Status of the Number of Approval (Notification) by Drug Type (2013~2021)

(including revoked·withdrawn items)

(Unit: Number of items)

Category	2013	2014	2015	2016	2017	2018	2019	2020	2021
ETC drugs	1,669	2,090	2,289	2,280	1,573	1,514	4,139	2,525	1,542
(Year-on-year increase, %)		25.2%	9.5%	-0.4%	-31.0%	-3.8%	173.4%	-39.0%	-38.9%
OTC drugs	427	726	626	481	476	532	670	704	450
(Year-on-year increase, %)		70.0%	-13.8%	-23.2%	-1.0%	11.8%	25.9%	5.1%	-36.1%
Drug substances	114	113	99	84	55	75	71	69	83
(Year-on-year increase, %)		- 0.9%	-12.4%	-15.2%	-34.5%	36.4%	-5.3%	-2.8%	20.3%
Medicinal herbs	186	178	1,909	983	420	361	1,307	198	195
(Year-on-year increase, %)		- 4.3%	972.5%	-48.5%	-57.3%	-14.0%	262.0%	-84.9%	-1.5%
Total	2,396	3,107	4,923	3,828	2,524	**2,482**	**6,187**	**3,496**	**2,270**

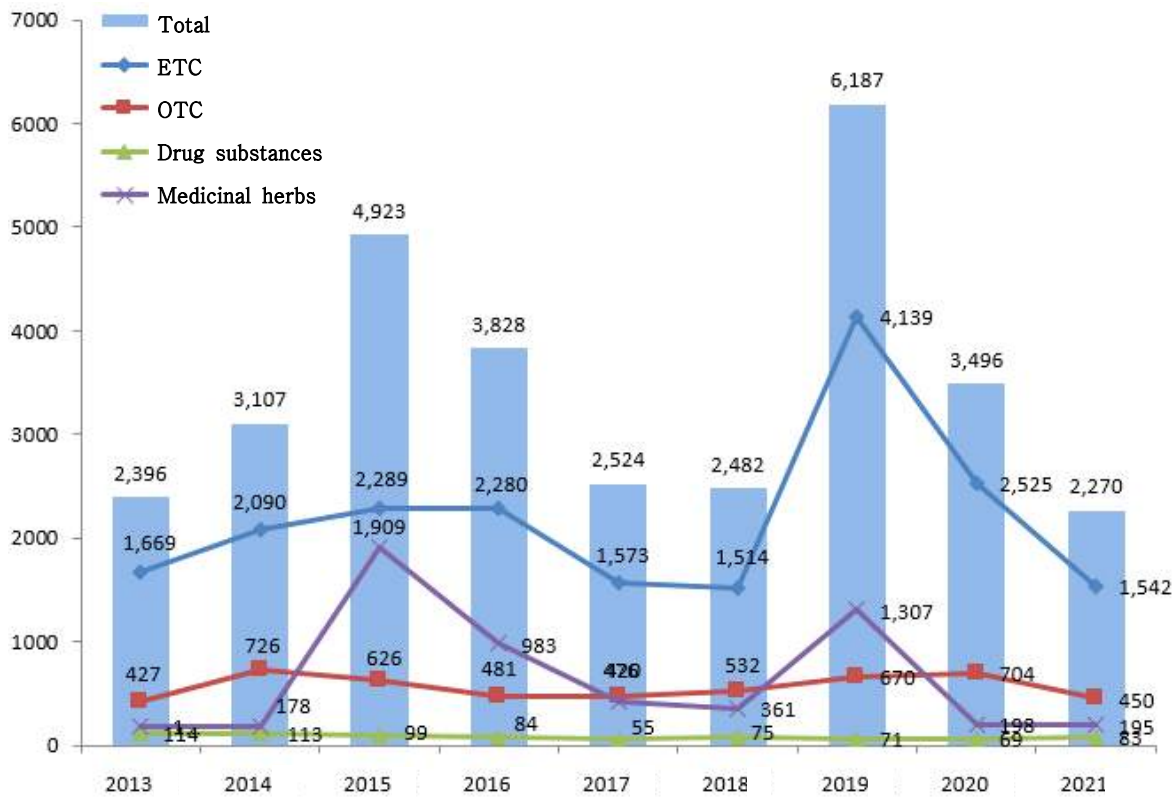

Figure 2. Approval (Notification) by Drug Type (2013~2021)

1.2. Approval of New Drugs

In 2021, a total of 37 new drugs were approved, i.e., 23 chemical drugs (4 manufactured, 19 imported); 11 biopharmaceuticals (3 manufactured, 8 imported); 2 advanced biological products (2 imported); and an herbal (oriental) medicine (1 manufactured). In the case of new drug substances, 28 were approved, i.e., 15 chemical drugs; 10 biophamaceuticals; 2 advanced biological products; and an herbal (oriental) medine (See Table 12, Table 15 for the entire list).

Similar to previous years, imported new drugs accounted the majority(78.4%).

Table 12. Approval Status of New Drugs in 2021

(Unit: Number of items)

Category	Total [Number of ingredients]	Chemical drugs	Biopharma-ceuticals	Advanced biolgical products	Herbal (oriental) medicine
Total	37[1] (100.0%) [28 (100.0%)]	23[2] [15]	11 [10]	2 [2]	1 [1]
Manufac-tured	8 (21.6%) [8 (28.6%)]	4 [4]	3 [3]	0 [0]	1 [1]
Imported	29 (78.4%) [20 (71.4%)]	19 [11]	8 [7]	2 [2]	0 [0]

1) Out of 37 items, 4 items were designated as both orphan and new drug.

2) In 2021, 22 chemical drugs were newly approved, and 2 items were designated as new drugs through post-approval changes [see Table 15]

New drugs have been actively developed for the past three years since 2019, maintaining an upward trend (see Table 13 and Figure 3).

According to the analysis of the new drugs that were approved in 2021, imported items accounted for 78.4% and manufactured items accounted for 21.6%. This shows that the importation of new drugs remains to have a significant impact on the total number of new drugs. For new substances, imported items accounted for 71.4% and manufactured items accounted for 28.6%. This indicates that the majority of the new substances were developed with new drugs that were imported.

For new drugs developed in Korea, 1~2 items were approved each year (5 items were approved in both 2015 and 2021). Since there were no domestically developed new drugs that were approved in 2019 and 2020, the number of items that were approved in 2021 was quite significant (5 items).

Table 13-1. Approval Status of Chemical Drugs, Biopharmaceuticals, Advanced Biological Products and Herbal (Oriental) medicines(2010~2021)

(including revoked·withdrawn items)

(Unit: Number of items)

Category		2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
Number of approved items[1)]		49	31	17	23	49	34	25	29	15	35	40	37
(Number of new drug ingredients)		(26)	(22)	(14)	(15)	(27)	(19)	(10)	(18)	(12)	(21)	(20)	(28)
Chemical drugs	Domestically developed new drugs	1	2	2	1	1	5	1	1	2	0	0	2
	Manufactured	3	8	3	3	3	6	2	1	2	4	5	4
	Imported	43	17	10	13	38	18	19	16	9	24	29	19
Biopharma-ceuticals	Domestically developed new drugs	0	0	0	0	0	0	0	1	0	0	0	2
	Manufactured	0	0	0	0	0	0	0	1	0	0	0	3
	Imported	1	6	4	6	8	10	4	11	4	7	6	8
Advanced Biological products	Domestically developed new drugs	-	-	-	-	-	-	-	-	-	-	-	0
	Manufactured	-	-	-	-	-	-	-	-	-	-	-	0
	Imported	-	-	-	-	-	-	-	-	-	-	-	2
Herbal (oriental) medicines	Domestically developed new drugs	0	0	0	0	0	0	0	0	0	0	0	1
	Manufactured	0	0	0	0	0	0	0	0	0	0	0	1
	Imported	2	0	0	1	0	0	0	0	0	0	0	0

1) The number of new drugs approved in the corresponding year, including items designated as new drugs through post-approval changes (2 chemical drugs, 1 biopharmaceutical)

2) The number of manufactured and marketed items includes the number of domesttically developed new drugs

Table 13-2. Approval Status of New Drugs by Year (2010~2021)

(including revoked·withdrawn items)

(Unit: Number of items)

Category	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
Manufac-tured (11.7%)	3 (6.1%)	8 (25.8%)	3 (17.6%)	3 (13.0%)	3 (6.1%)	6 (17.6%)	2 (8.0%)	2 (6.9%)	2 (13.3%)	4 (11.4%)	5 (12.5%)	8 (21.6%)
Imported (88.3%)	46 (93.9%)	23 (74.2%)	14 (82.4%)	20 (87.0%)	46 (93.9%)	28 (82.4%)	23 (92.0%)	27 (93.1%)	13 (86.7%)	31 (88.6%)	35 (87.5%)	29 (78.4%)
Number of items	49	31	17	23	49	34	25	29	15	35	40	37

Looking into the approval status of new drugs by therapetuic class, 19 nervous system therapeutics accounted for the majority of approved items in 2010, 6 genitourinary system drugs (3 ingredients) in 2011, 6 anti-tumor agents (4 ingredients) in 2012, 6 anti-diabetes agents (3 ingredients) in 2013, and 16 nervous system therapeutics (5 ingredients) in 2014. Nervous system therapeutics (3 ingredients) and anti-diabetes agents (4 ingredients) accounted for the majority in 2015, 14 anti-tumor agents (7 ingredients) in 2016, 11 anti-tumor agents (5 ingredients) in 2017, and 4 items of other chemotherapeutic agents (2 ingredients) in 2018. anti-tumor agents accounted for the majority of approved items in 2019 and 2020 as 13 of them were approved in both years (5 ingredients in 2019 and 6 in 2020). anti-tumor agents accounted for the majority in 2021 as well as 6 itmes (6 ingredients) were approved. Looking at the cumulative number of the approved new drugs for the past 12 years, anti-tumor agents, nervous system therapeutics, and chemotherapeutic and circulatory system agents accounted for the majority, with the number of 91 items, 70 items and 34 items respectively (see Table 14).

Table 14. Therapeutic Class of New Drug Approval by Year (2010~2021)

(including revoked·withdrawn or new drugs with post-approval changes)

(Unit: Number of items)

Category	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021		Total
												Approval	Post-approval change	
Nervous system	19	0	1	1	16	8	2	0	0	9	9	5	0	70
anti-tumor agents	8	3	6	4	7	5	14	11	1	13	13	4	2	91
Anti-diabetes	1	3	1	6	11	8	0	0	2	0	0	0	0	32
Chemotherapeutic agents	7	1	1	0	2	5	2	3	4	4	5	0	0	34
Circulatory system	5	3	0	0	1	2	6	9	1	0	3	4	0	34
Respiratory system	3	1	0	0	4	1	2	1	0	1	0	2	0	15
Genitourinary system	0	6	0	2	0	0	0	0	0	0	0	0	0	8
Sensory system	1	1	2	0	3	0	0	0	0	3	0	1	0	11
Anti-allergic	0	1	2	3	1	0	0	8	2	1	3	3	0	24
Others	5	12	4	7	4	9	6	3	5	8	7	15	1	87
Total	**49**	**31**	**17**	**23**	**49**	**38**	**32**	**35**	**15**	**39**	**40**	**34**	**3**	**405**
												37		

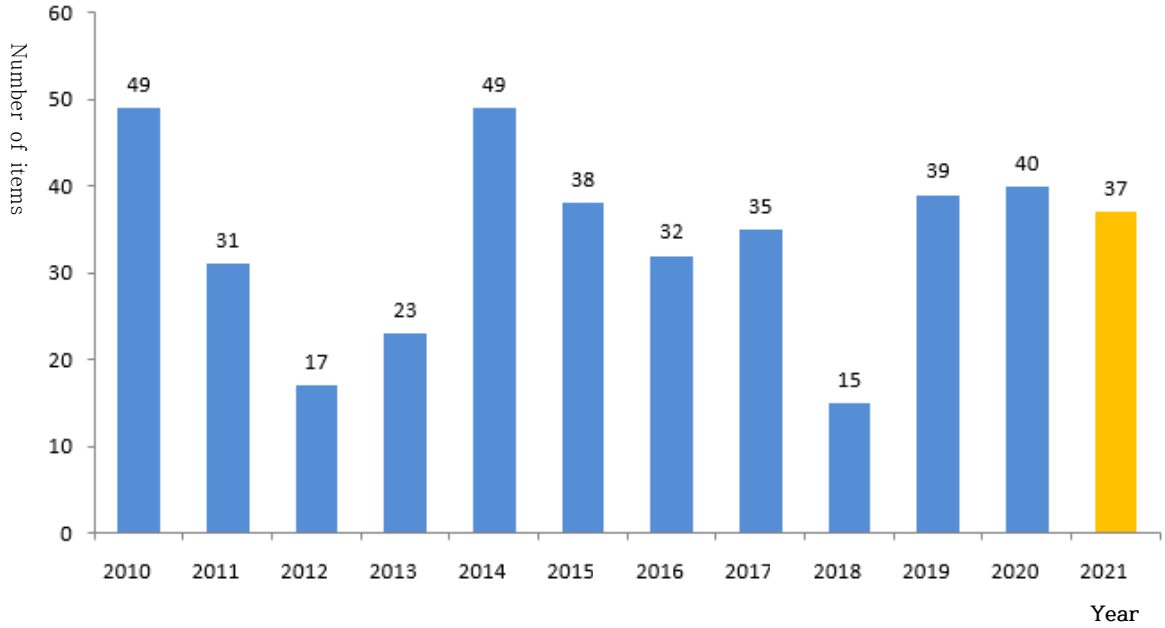

Figure 3. Approval Status of New Drugs by Year (2010~2021) (including revoked·withdrawn items of new drugs with post-approval changes)[See Table 15]

Table 15. List of Approved New Drugs in 2021

(including items designated as new drugs through post-approval changes)

☐ Chemical drugs, ☐ Biopharmaceuticals, ☐ Advanced Biological products, ☐ Herbal (oriental) medicines

No.	Manufactured/ Imported	Product name	Company	Approval date	Classification	Efficacy/Effectiveness (partially omitted)
1	Imported	Galafold Capsule (Migalastat HCl)	Handok Inc.	(Designated as new drug) (2021-01-28) 2017-12-20	Miscellaneous digestive system drugs	Long-term treatment of adolescents aged 16 years or older and adults diagnosed with Fabry disease (α-galactosidaseA deficiency) with an amenable mutation
2	Imported	Bavencio (Avelumab)	Merck Ltd.	(Designated as new drug) (2021-08-05) 2019-03-22	anti-tumor agents	1. Monotherapy for the treatment of metastatic Merkel cell carcinoma in adults 2. First-line monotherapy in adult patients with locally advanced or metastatic urothelial cell carcinoma whose disease did not progress through platinum-based chemotherapy
3	Manufactured	Byfavo Inj. 50mg (Remimazolam Besylate)	Hana pharm	2021-01-07	General anesthetics	Induction and maintenance of general anesthesia in adults
4	Manufactured (Domestically developed)	Yuhan Lazertinib Tablet (Lazertinib Mesylate Monohydrate)	Yuhan Corporation	2021- 01-18	anti-tumor agents	Treatment of patients with EGFR T790M mutation-positive locally advanced or metastatic non-small cell lung cancer previously treated with EGFR-TKI The efficacy of this drug was based on the response rate and duration of response, and there are no data demonstrating improvement in survival.
5	Imported	Vyzulta ophthalmic solution 0.024% (Latanoprostene bunod)	Bausch Health Korea Co., Ltd.	2021-02-05	Ophthalmic preparations	Intraocular pressure reduction of the following diseases: Open angle glaucoma, ocular hypertension

No.	Manufactured/ Imported	Product name	Company	Approval date	Classification	Efficacy/Effectiveness (partially omitted)
6	Manufactured (Domestically developed)	Regkirona 960mg (Regdanvimab) (monoclonal antibody, genetic recombination)	Celltrion Pharm, Inc.	2021-02-05	Miscellaneous respiratory drugs	Treatment of all patients with mild to moderate severity in the high-risk group who meet all of the following criteria as adults diagnosed with COVID-19 through PCR test, etc. 1) Those whose oxygen saturation exceeds 94% in indoor air 2) Those who do not need supplemental oxygen supply 3) Those who developed symptoms within 7 days before administration
7	Imported	Calquence Capsule (Acalabrutinib)	AstraZeneca Korea	(Designated as new drug) (2021-09-10)2021-02-05	anti-tumor agents	1. Combination or mono-therapy with obinutuzumab in previously untreated chronic lymphocytic leukemia patients aged 65 years or older or patients younger than 65 years with comorbidities 2. Monotherapy in patients that have gone through more than one treatment for chronic lymphocytic leukimia
8	Manufactured	Vaxzevria solution for injection(SARS-CoV-2 virus vector vaccine)	AstraZeneca Korea	2021-02-10	Vaccines	Prevention of COVID-19 caused by SARS-CoV-2 virus in 18 years of age or older
9	Imported	Takhzyro PFS (Lanadelumab)	Takeda Pharma-ceuticals Co., Ltd.	2021-02-26	Miscellaneous circulatory system drugs	Routine prevention of hereditary angioedema attacks in adults and adolescents (ages 12 years and older)
10	Imported	Comirnaty Injection(Tozinameran)(SARS CoV-2 mRNA Vaccine)	Pfizer Korea Ltd.	2021-03-05	Vaccines	Prevention of COVID-19 caused by SARS-CoV-2 virus in children 12 years of age or older
11	Imported	Kymriah (Tisagenlecleucel)	Novartis Korea	2021-03-05	anti-tumor agents	1. Treatment of leukemia relapsed after transplantation or secondary relapse and subsequent relapsed leukemia or refractory B-cell acute lymphoblastic leukemia (ALL) in pediatric patients up to 25 years of age and young adult patients 2. Treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after two or more systemic therapies
12	Manufactured (Domestically developed)	Rolontis Prefilled Syringe Inj. (Eflapegrastim)	Hanmi Pharm. Co., Ltd.	2021-03-18	Miscellaneous blood and body fluid drugs	Reduced duration of severe neutropenia in patients receiving cytotoxic chemotherapy for solid cancer and malignant lymphoma

No.	Manufactured/ Imported	Product name	Company	Approval date	Classification	Efficacy/Effectiveness (partially omitted)
13	Imported	COVID-19 Vaccine Janssen (SARS-CoV-2 virus vector vaccine)	Janssen Korea Ltd.	2021-04-07	Vaccines	Prevention of COVID-19 caused by SARS-CoV-2 virus in those 18 years of age or older
14	Manufactured (Domestically developed)	BRONPASS(Prepared Rehmannia Root·Moutan Root Bark·Schisandra Fruit· Asparagus Tuber·Scutellaria Root· Apricot Kernel·Stemonae Radix soft ext.(1.4～1.7→1)·Corn starch mixed dried products(4.8:1)	Hanlim Pharm. Co., Ltd.	2021-04-09	Miscellaneous respiratory drugs	Acute bronchitis
15	Imported	Aklief cream 0.005%(Trifarotene)	Galderma Korea Co., Ltd.	2021-04-27	Emollients (including escharotic agents)	Local treatment of moderate acne with comedones, papules, and pustules in patients that are 9 or older (face or body)
16	Imported	Piqray (Alpelisib)	Novartis Korea	2021-05-13	anti-tumor agents	Combined administration with fulvestrant for hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative, and PIK3CA mutation -positive postmenopausal women and advanced or metastatic breast cancer in men whose disease progressed after endocrine therapy
17	Imported	Moderna COVID-19 vaccine (SARS corona virus-2 mRNA vaccine) → (Product name changed to) SPIKE(SARS corona virus-2 mRNA vaccine)	GC Pharma	2021-05-21	Vaccines	Prevention of COVID-19 caused by SARS-CoV-2 virus in 18 years of age or older
18	Imported	Zolgensma (Onasemnogene abeparvovec)	Novartis Korea	2021-05-28	Miscellaneous central nervous system drugs	Patient with Spinal Muscular Atrophy (SMA) with a biallelic mutation in the Survival Motor Neuron 1 (SMN1) gene falling under any of the following: - Clinically diagnosed with Type 1 - Contains three or less copies of Survival Motor Neuron 2 (SMN2) gene

No.	Manufactured/ Imported	Product name	Company	Approval date	Classification	Efficacy/Effectiveness (partially omitted)
19	Imported	Evrenzo tablets 150mg (Roxadustat)	AstraZeneca Korea	2021-07-09	Miscellaneous blood and body fluid drugs	Treatment of symptomatic anemia in patients with chronic kidney disease
20	Imported	Evrenzo tablets 50mg (Roxadustat)				
21	Imported	Evrenzo tablets 100mg (Roxadustat)				
22	Imported	Evrenzo tablets 70mg (Roxadustat)				
23	Imported	Evrenzo tablets 20mg (Roxadustat)				
24	Imported	Ajovy solution for injection in Pre-Filled Syringe (Fremanezumab, genetic recombination)	Teva-Handok	2021-07-27	Central nervous system drugs	Prevention of migraine in adults
25	Imported	Ajovy solution for injection in Autoinjector (Fremanezumab, genetic recombination)				
26	Imported	Shingrix powder and suspension for suspension for injection [Herpes zoster vaccine (recombinant, adjuvanted)]	GlaxoSmith Kline	2021-09-06	Vaccines	Prevention of herpes zoster - Adults 50 years of age or older - Persons 18 years of age or older who have or are expected to have a high risk of herpes zoster from immunodepression or immunosuppression due to disease or treatment (eg, autologous hemato-poietic stem cell trans-plantation, solid cancer, blood cancer, solid organ transplant patient)
27	Manufactured	FACBC injection (Fluciclovine(18F))	DuchemBio Co., Ltd.	2021-09-17	Radiopharma-ceutical	Used for positron emission tomography (PET) in the following cases. Confirmation of prostate cancer through the use of positron tomography (PET) in adult males suspected of recurrence of prostate cancer due to elevation of Prostate-Specific Antigen (PSA) in blood after previous treatment for prostate cancer

No.	Manufactured/ Imported	Product name	Company	Approval date	Classification	Efficacy/Effectiveness (partially omitted)
28	Imported	Nerlynx Tablet (Neratinib maleate)	Bixink Therapeu-tics Co., Ltd.	2021-10-19	anti-tumor agents	Administered alone as an extended adjuvant to patients with hormone receptor-positive and HER2-positive early breast cancer within 1 year of completing trastuzumab-based therapy as postoperatively adjuvant therapy previously
29	Imported	Cibinqo tablet 100mg (Abrocitinib)	Pfizer Korea Ltd.	2021-11-23	Certified therapeutic agent (including nonspecific immunosuppressant)	Treatment of moderate to severe atopic dermatitis in adults and adolescents 12 years of age or older subject to systemic therapy
30	Imported	Cibinqo tablet 200mg (Abrocitinib)				
31	Imported	Cibinqo tablet 50mg (Abrocitinib)				
32	Imported	Verquvo 2.5mg (Vericiguat(anaplastic))	Bayer Korea Ltd.	2021-11-30	Miscellaneous circulatory system drugs	Chronic heart failure: Reducing the risk of death from cardiovascular disease and hospitalization for heart failure in symptomatic chronic heart failure patients with a lower left ventricular ejection fraction of less than 45% who have recently been hospitalized for heart failure or received outpatient intravenous diuretics This drug is administered in combination with other heart failure medicines.
33	Imported	Verquvo 5mg (Vericiguat(anaplastic))				
34	Imported	Verquvo 10mg (Vericiguat(anaplastic))				
35	Imported	DYSVAL Capsule 40mg (Valbenazine ditosylate)	Mitsubishi Tanabe Pharma Korea Co.,Ltd.	2021-11-30	Miscellaneous central nervous system drugs	Improving symptoms of tardive dyskinesia in adults
36	Imported	OZANEX Cream (Ozenoxacin)	Bukwang Pharm Co.,Ltd	2021-12-10	Suppurative disorder agents	1. Effective for Staphylococcus aureus (S. aureus), Streptococcus pyogenes (S. pyogenes) 2. Indication short-term topical treatment of impetigo
37	Manufactured (Domestically developed)	FEXUCLUE Tablet 40mg (Fexuprazan hydrochloride)	Daewoong Pharma-ceutical Co., Ltd.	2021-12-30	Peptic ulcer agents	Treatment of erosive gastro-esophageal reflux disease

* Detailed approval information (efficacy/effectiveness, mode of administrations/dose, and precautions for use) is available at http://nedrug.mfds.go.kr

Table 16. List of New Drugs Developed in Korea (1999~2021) (including withdrawn items)

No.	Product	Company	Active Ingredient	Efficacy/ Effectiveness	Remarks
1	Sunpla injection	SK Chemicals	Heptaplatin	Anticancer drug (gastric cancer)	1999.7.15 (1993.7.20)
2	Easyef SOLN 0.005% 0.5mg/ml	DAEWOONG PHARMACEUTICAL CO.,LTD.	Human epidermal cell growth factor	Diabetic, foot ulcer treatment	2001.5.30 (1997.3.4)
3	Milican Injection	DONGWHA PHARM. CO., LTD.	Holmium Nitrate-166	Anticancer drug (hepatic cancer)	2001.7.6 (1997.5.28)
4	Q-roxin Tab.	JW Pharmaceutical	Balofloxacin	Antimicrobial agent (antibiotic)	2001.12.17 (1993.5.6)
5	Factive Tab. 320mg	LG Chem Ltd.	Gemifloxacin mesylate	Antimicrobial agent (antibiotic)	2002.12.27 Approved by US FDA (2003.4.4)
6	Apitoxin Injection	GUJU PHARM.CO.,LTD.	Dry honey bee poison	Arthritis treatment	2003.5.3 (1999.11.29)
7	Pseudovaccine Injection	CJ Healthcare Corp. → (name change)HK inno.N	Pseudomonas vaccine dried tablet	Pseudomonas aeruginosa preventive vaccine	2003.5.28 (1995.1.26)
8	Camtobell Inj.	Chong Kun Dang Pharm.	Belotecan	Anticancer drug	2003.10.22
9	Revanex Tablet	Yuhan Corporation	Revaprazan HCl	Anti-ulcer agent	2005.9.15
10	Zydena Tablet	DONG-A ST	Udenafil	Erectile dysfunction treatment	2005.11.29
11	Levovir Cap.	Bukang Pharm Co.,Ltd	Clevudine	Hepatitis B treatment	2006.11.13 (2001.6.13)
12	Pelubi Tablet	Daewon Pharm. Co., Ltd	Pelubiprofen	Osteoarthritis treatment	2007.4.20
13	Mvix Tab	SK Chemicals	Mirodenafil HCl	Erectile dysfunction treatment	2007.7.18
14	NOLTEC Tab.	IL-YANG PHARMACEUTICAL CO., LTD	Ilaprazole	Anti-ulcer agent	2008.10.28
15	Kanarb Tablet	Boryung Pharmaceutical	Fimasartan potassium trihydrate	Antihypertensive drug	2010.9.9
16	PYRAMAX Tablet	ShIN POONG PHARM. CO., LTD.	Pyronaridine tetraphosphate/ artesunate	Malaria treatment	2011.8.17
17	Zepeed Tab.	JW Pharmaceutical	Avanafil	Erectile dysfunction treatment	2011.8.17
18	SUPECT Caps.	IL-YANG PHARMACEUTICAL CO., LTD	Radotinib HCl	Anticancer drug (leukemia)	2012.1.5
19	Zemiglo Tab. 50mg	LG Chem Ltd.	Gemigliptin tartrate 1.5-hydrate	Antidiabetics	2012.6.27
20	Duvie Tab. 0.5mg	Chong Kun Dang Pharm.	Lobeglitazone sulfate	Antidiabetics	2013.7.4
21	RIA Inj.	Gem & KAEL	Tertomotide hydrochloride	Anticancer drug	2014.9.15
22	Acelex Capsule 2mg (Polmacoxib)	CrystalGenomics, Inc.	Polmacoxib	Osteoarthritis treatment	2015.2.5
23	Zaborlante Tab.	DONGWHA PHARM. CO., LTD.	Zabofloxacin D-Aspartate Hydrate	Antimicrobial agent (antibiotic)	2015.3.20
24	Sivextro Tablet	DONG-A ST	Tedizolid phosphate	Antimicrobial agent (antibiotic)	2015.4.17
25	Sivextro Injection	DONG-A ST	Tedizolid phosphate	Antimicrobial agent (antibiotic)	2015.4.17
26	Suganon Tablet	DONG-A ST	Evogliptin tartrate	Antidiabetics	2015.10.2
27	Olita Tab. 200mg	Hanmi Pharm. Co., Ltd.	Olmutinib dihydrochloride monohydrate	Anticancer drug	2016.5.13
28	BESIVO Tab.	ILDONG PHARMACEUTICAL CO., LTD.	Besifovir dipivoxil maleate	Hepatitis B treatment	2017.5.15
29	Alzavue injection	FutureChem Co., Ltd.	Florapronol (18F) solution	Adjuvant diagnosis of Alzheimer's	2018.2.2
30	K-CAP Tab	CJ Healthcare Corp. → (name change)HK inno.N	Tegoprazan	Gastroesophageal reflux disease treatment	2018.7.5
31	Regkirona	Celltrion Pharm, Inc.	Regdanvimab	COVID-19 treatments	2021.2.5

No.	Product	Company	Active Ingredient	Efficacy/ Effectiveness	Remarks
32	Rolontis Prefilled Syringe Inj.	Hanmi Pharm. Co., Ltd.	Eflapegrastim	Neutropenia	2021.3.18
33	BRONPASS	Hanlim Pharm. Co., Ltd.	Prepared Rehmannia Root·Moutan Root Bark·Schisandra Fruit·Asparagus Tuber·Scutellaria Root·Apricot Kernel·Stemonae Radix soft ext.(1.4～1.7→1)·Corn starch mixed dried products(4.8:1)	Acute bronchitis treatments	2021.4.9
34	FEXUCLUE Tablet	Daewoong Pharmaceutical Co., Ltd.	Fexuprazan hydrochloride	Esophageal reflux treatments	2021.12.30

※ Excluding revoked items

1.3. Approval of Orphan Drugs

In 2021, 22 orphan drugs were approved, and they consisted of 15 chemical drugs, 4 biopharmaceuticals and 3 advanced biological products. Additionally, 19 ingredients were approved, consisting of 12 chemical drugs, 4 biopharmaceuticals and 3 advanced biological products (see Table 17).

Table 17. Approval Status of Orphan Drugs in 2021

(Unit: Number of items)

Category	Total (Number of ingredients)	Chemical drugs	Biopharma-ceuticals	Advanced biological products	Herbal (oriental) medications
Imported	22 (19)	15 (12)	4 (4)	3 (3)	0 (0)
New orphan drugs	0	0	0	0	0

The approval status of orphan drugs since 2010 indicates that a similar amount of items were approved from 2010 to 2014. However, in 2015, 49 items were approved, which was 1.8 times the five-year average (27 items). This spike seems to be due to the change in requirements for product approval in July 2015; preliminary evaluation of the GMP implementation status, review of specifications and test methods, and submission of risk management plans for orphan drugs (see Table 18 and Figure 4). Since the implementation in July, the number of approved orphan drugs decreased. However, in 2020 and 2021, 28 items and 22 items were approved respectively, showing similarity to the five-year average mentioned above.

Table 18. Approval Status of Orphan Drugs by Year (2010~2021)

(including revoked·withdrawn items)

(Unit: number of items)

Category	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
Orphan Drugs	26	26	27	28	28	49	34	18	17	11	28	22

Furthermore, a total of 24 ingredients were newly designated as orphan drugs in 2021 (see Table 19).

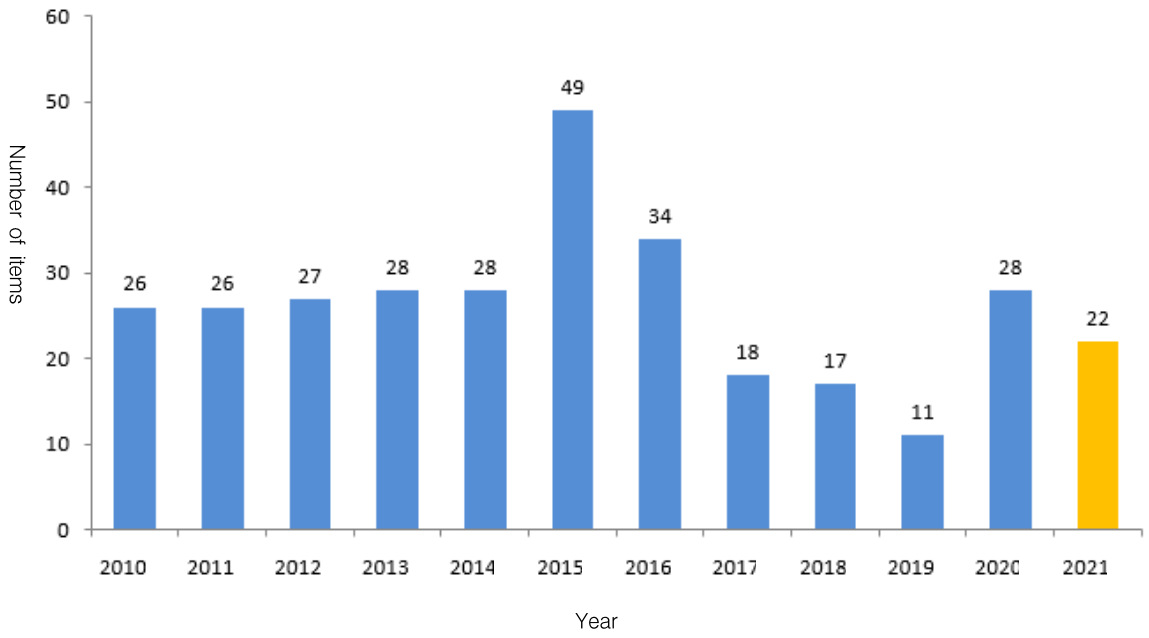

Figure 4. Approval Status of Orphan Drugs (2010~2021)

Table 19. Ingredients of Newly Designated Orphan Drugs in 2021

No.	Ingredient (generic name)	Indication
1	Lisocabtagene maraleucel (injection)	Treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade IIIb after two or more systemic therapies
2	Fedratinib (oral)	Treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis (chronic idiopathic myelofibrosis), myelofibrosis after polycythemia vera, or myelofibrosis after essential thrombocytosis previously treated with ruxoritinib
3	Selpercatinib (oral)	1. Metastatic RET (REarranged during Transfection) fusion-positive non-small cell lung cancer 2. Advanced or metastatic RET-mutated medullary thyroid cancer that requires systemic therapy 3. Advanced or metastatic RET fusion-positive thyroid cancer that requires systemic therapy and refractory to radioactive iodine
4	Idecabtagene vicleucel(injection)	Treatment of adult patients with multiple myeloma who have previously received at least three treatments, including immunomodulatory agents, proteasome inhibitors, and anti-CD38 antibody therapies.
5	Amivantamab (injection)	Treatment of patients with locally advanced or metastatic non-small cell lung cancer with an epidermal growth factor receptor (EGFR) exon 20 insertion mutation whose disease has progressed during or after platinum-based chemotherapy
6	Human protein C concentrate (injection)	Substitution therapy to prevent and treat of thrombosis and purpura fulminant in patients with severe congenital protein C deficiency
7	Sotorasib (oral)	KRAS p. G12C mutation locally advanced and metastatic non-small cell lung cancer in patients who received more than one treatment
8	Fordadistrogene movaparvovec (injection)	Severe Duchenne muscular dystrophy
9	Pralsetinib(oral)	1. Metastatic RET (REarranged during Transfection) fusion-positive non-small cell lung cancer 2. Advanced or metastatic RET-mutated medullary thyroid cancer requiring systemic therapy 3. Advanced or metastatic RET fusion-positive thyroid cancer requiring systemic therapy and refractory to radioactive iodine
10	Luspatercept(injection)	1. Beta thalassemia in adults requiring red blood cell transfusion 2. Anemia in adults requiring red blood cell transfusion following failure of ESA therapy - Very low-risk, low-risk, moderate-risk myelodysplastic syndrome with ringed sideroblast (MDS-RS) or - Myelodysplastic/myeloproliferative tumor accompanying very low-risk, low-risk, and moderate-risk ringed sideroblast and thrombocytosis (MDS/MPN-RS-T)
11	Asciminib(oral)	Treatment of adult patients with Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML) in the chronic phase previously treated with two or more tyrosine kinase inhibitors.

No.	Ingredient (generic name)	Indication
12	Azacitidine(oral)	Maintenance therapy in adult patients with acute myeloid leukemia who achieved complete remission (CR) or complete remission with incomplete hematologic recovery (CRi) after induction therapy with or without consolidation therapy, and unsuitable for hematopoietic stem cell transplantation (HSCT) therapy
13	Sacituzumab govitecan(injection)	Treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC) who received two or more prior systemic therapies(in which at least one of of the treatment was for metastatic disease)
14	Avalglucosidase alfa(injection)	Long-term enzyme replacement therapy in patients diagnosed with Pompe disease (acid alpha-glucosidase deficiency)
15	Cemiplimab (injection)	Locally advanced or metastatic squamous cell carcinoma not subject to curative surgery or radical radiation therapy
16	CPX-351(Liposomes containing cytarabine and daunorubicin)(injection)	1. Treatment of newly diagnosed treatment-related acute myeloid leukemia (t-AML) in adults 2. Treatment of newly diagnosed acute myeloid leukemia with myelodysplasia-associated changes (AML-MRC) in adults
17	Susoctocog alfa(injection)	Treatment of bleeding in adult patients with acquired hemophilia A
18	Enfortumab vedotin(injection)	Treatment of adult patients with locally advanced or metastatic urothelial cancer who have previously been treated with PD-1 or PD-L1 inhibitors and platinum-based chemotherapeutic agents
19	Maribavir(oral)	Treatment of post-transplant cytomegalovirus (CMV) infection and disease in adult patients resistant or refractory to one or more of ganciclovir, valganciclovir, foscanet, or cidofovir
20	Bulevirtide(injection)	Treatment of chronic hepatitis D virus infection in adult patients with compensated liver disease
21	Ponesimo(oral)	Treatment of adult patients with relapsing multiple sclerosis
22	Spesolimab(injection)	Systemic pustular psoriasis
23	Pemigatinib(tablet)	Locally advanced or metastatic cholangiocarcinoma in adults with fusion or rearrangement of fibroblast growth factor receptor 2 (FGFR2) who received systemic therapy at least once in the past
24	Fostamatinib(tablet)	Thrombocytopenia in adults with chronic immune (idiopathic) thrombocytopenia (ITP) who have had an insufficient response to previous treatment (including corticosteroids, immunoglobulin, splenectomy, elthrombopacolamine, or lomiflostim)

1.4. Approval and Notification Status by Major Therapeutic and Classification

In descending order, the ratio of drug products that were approved and notified in 2021 by therapeutic class are as follows; circulatory system drugs such as hypertension drugs (26.3%), metabolic drugs such as anti-diabetic drugs (19.4%), nervous system drugs such as dementia drugs (12.2%), digestive system drugs such as stomach ulcer drugs (8.6%), and blood and body fluid drugs such as anticoagulant drugs (8.4%) (see Table 20 and Figure 5).

Table 20. Status of the Number of Approved and Notified Items by Therapeutic Class in 2021

(including revoked·withdrawn items)

(Unit: Number of items)

Classification / Total	Nervous system	Circulatory system	Digestive system	Metabolism		Antibiotics	Chemo-therapy agents	Blood and body fluid drugs	Allergic	Others
				Others	Antidia-betics					
1,992	243 (12.2%)	523 (26.3%)	171 (8.6%)	52 (2.6%)	335 (16.8%)	20 (1.0%)	8 (0.4%)	168 (8.4%)	38 (1.9%)	434 (21.8%)
				387 (19.4%)						

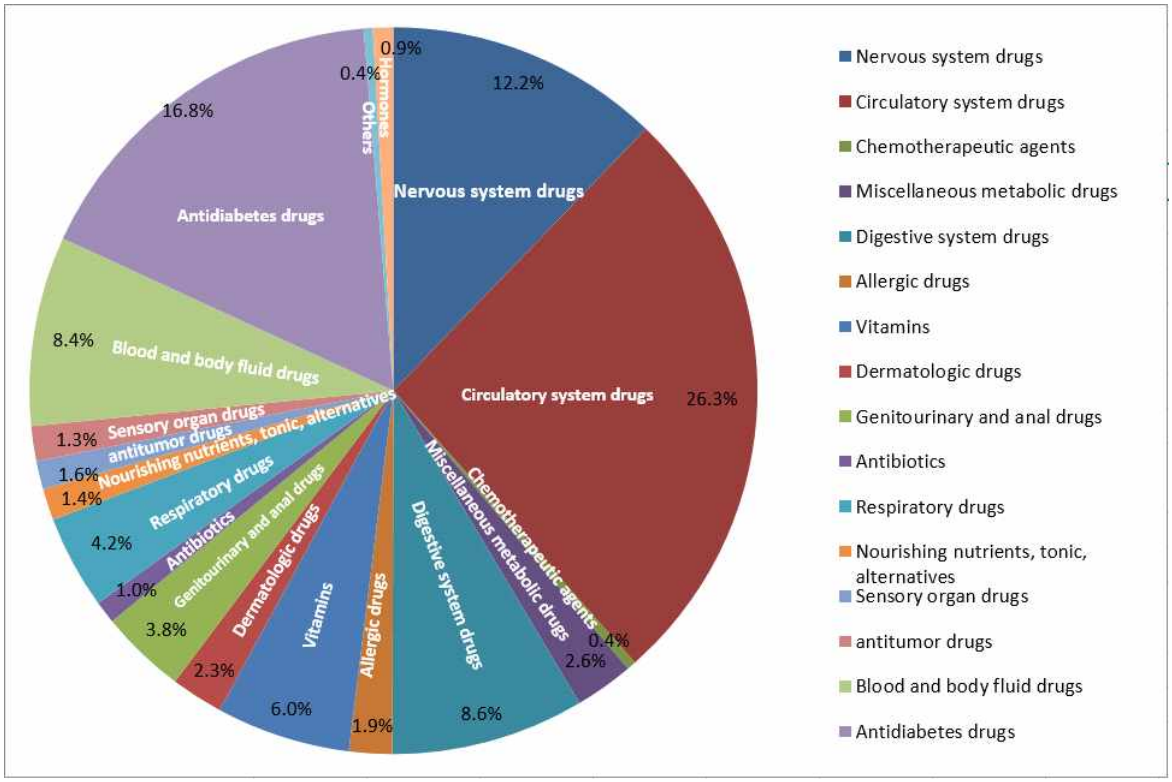

Figure 5. Distribution Status of Approved (Notified) Drugs by Major Therapeutic Class in 2021

According to the analysis of the approval and notification status by therapeutic class, the circulatory system drugs, metabolic drugs (including metabolic agents and diabetes related drugs), nervous system drugs and digestive system drugs accounted for the majority in 2021, as it did in 2020 (see Figure 6).

Similar to 2020, circulatory system drugs accounted for the majority of the drugs that were approved and notified in 2021. Additionally, the number of circulatory drugs that were approved or notified in 2021 showed an increase by 7% to that of 2020. Arteriosclerosis agents, miscellaneous circulatory system drugs, and blood pressure-lowering agents accounted for the majority of the circulatory system drugs (98.9%). Metabolic drugs accounted

for the second majority, and the majority (96.6%) of them were diabetic related drugs and other metabolic drugs (including Liver disease drugs to Antidiabetic drugs from Table 22) (see Figure 6 and Table 22).

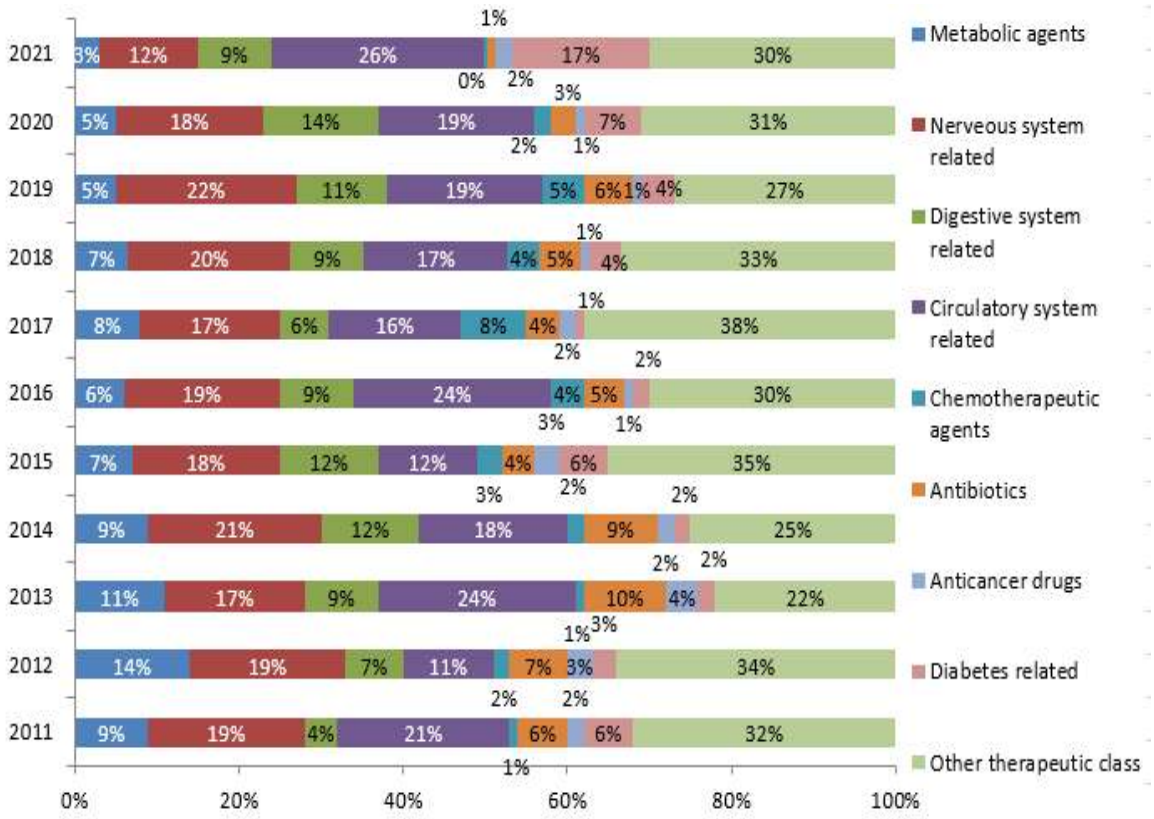

Figure 6. Ratio of Approved (Notified) Drugs by Drug Therapeutic Class by Year (2011~2021)

Further analyzing by effiacacy, it is shown that the arteriosclerosis drugs were within the top 5 category from 2018 to 2021, and accounted for 18.9% in 2021 (377 items). Antidiabetics (16.8%, 335 items), anticoaulators (8.0%, 160 items)and miscellaneous circulatory system drugs (6.2%, 123 items) followed in order (see Table 21).

Table 21. Detailed Classification of Top 5 Approved Items (2017~2021)

(including revoked·withdrawn items)

	2017		2018		2019		2020		2021	
	Detailed classification	Number of items	Detailed classification	Number of items	Detailed classification	Number of items	Detailed classification	Number of items	Detailed classification	Number of items
1	Miscellaneous chemotherapeu -tics	166 (8.1%)	Antipyretics, analgesics, and antiinflammatory drugs	152 (7.4%)	Antihypertensive	482 (10.0%)	Miscellaneous circulatory system drugs	240 (7.7%)	Antiarteriosclero -tic agents	377 (18.9%)
2	Antipyretics, analgesics, and antiinflammatory drugs	146 (7.1%)	Antihypertensive	145 (7.1%)	Miscellaneous central nervous system drugs	374 (7.8%)	Peptic ulcer agents	227 (7.3%)	Antidiabetics	335 (16.8%)
3	Antihypertensive	138 (6.7%)	Miscellaneous central nervous system drugs	128 (6.3%)	Antipyretics, analgesics, and antiinflammatory drugs	351 (7.3%)	Antidiabetics	221 (7.1%)	Anticoagulants	160 (8.0%)
4	Miscellaneous central nervous system drugs	112 (5.5%)	Antiarteriosclero -tic agents	117 (5.7%)	Peptic ulcer agents	340 (7.1%)	Antipyretics, analgesics, and antiinflammatory drugs	190 (6.1%)	Miscellaneous circulatory system drugs	123 (6.2%)
5	Miscellaneous metabolic drugs	112 (5.5%)	Miscellaneous metabolic drugs	102 (5.0%)	Antiarteriosclero -tic agents	261 (5.4%)	Antiarteriosclero -tic agents	175 (6.0%)	Antipyretics, analgesics, and antiinflammatory drugs	108 (5.4%)
	Number of drug products approved and notified in 2017	2,049 (100%)	Number of drug products approved and notified in 2018	2,046 (100%)	Number of drug products approved and notified in 2019	4,809 (100%)	Number of drug products approved and notified in 2020	3,110 (100%)	Number of drug products approved and notified in 2021	1,992 (100%)

Table 22. Status of Drug Product Approval and Notification by Major Therapeutic Class in 2021

Classification	Detailed classification	Number of items
Nervous system agents	General anesthetics	4
	Hypnotic sedatives	8
	Antiepileptics	15
	Antipyretics, analgesics, and anti-inflammatory drugs	108
	Antivertigo drugs	0
	Psychotropics	31
	Miscellaneous central nervous system drugs	65
	Local anesthetics	2
	Skeletal muscle relaxants	2
	Autonomic nervous system drugs	1
	Antispasmodics	5
	Diaphoretics, anhidrotics	1
	Miscellaneous peripheral nerve drugs	1
	Subtotal	243
Ophthalmology and ENT	Ophthalmic preparations	23
	Otic and nasal agents	2
	Subtotal	25
Circulatory system drugs, blood and body fluid drugs	Antiarrhythmic drugs	0
	Antihypertensives	17
	Capillary stabilizers	3
	Vasodilators	3
	Antiarteriosclerotic agents	377
	Miscellaneous circulatory system drugs	123
	Blood substitutes	0
	Hemostatics	2
	Anticoagulants	160
	Miscellaneous blood and body fluid drugs	6
	Subtotal	691
Respiratory organs and antiallergic drugs	Antihistamines	4
	Certified therapeutic agent(including nonspecific immunosuppressant) Non-specific immunogen preparations	34
	Miscellaneous antiallergic drugs	0
	Antitussive expectorants	27
	Inhalation treatment preparations	9
	Miscellaneous respiratory drugs	8
	Tuberculostatics	1
	Subtotal	83

Classification	Detailed classification	Number of items
Digestive system drugs	Dental and oral drugs	11
	Peptic ulcer agents	71
	Stomachics and digestives	21
	Antacids	13
	Emetics and antiemetics	5
	Cholagogues	1
	Probiotics	13
	Purgatives and clysters	18
	Miscellaneous digestive system drugs	18
	Subtotal	171
Urinary and reproductive system drug	Emmenagogues	1
	Contraceptives	8
	Genito-urinary agents (including venereal disease preventive drugs)	2
	Hemorrhoidal preparations	9
	Miscellaneous urogenital and anal organ drugs	56
	Subtotal	76
Metabolic drugs	Vitamin A and D preparations	10
	Vitamin B1 preparations	2
	Vitamin B preparations (excluding vitamin B1))	3
	Vitamin C and P preparations (excluding vitamin B1)	1
	Vitamin E and K preparations	1
	Multivitamin preparations (excluding multivitamin complex with A and D)	14
	Low-content vitamin and mineral preparations	2
	Miscellaneous vitamin preparations	86
	Calcium preparations	12
	Nourishing nutrients, tonic and alternatives	1
	Mineral preparations	3
	Protein and amino acid preparations	6
	Miscellaneous nourishing nutrients, tonic and alternatives	6
	Liver disease drugs	8
	Antidotes	3
	Gout preparations	0
	Enzyme preparations	3
	Comprehensive metabolic preparations	1
	Miscellaneous metabolic drugs	37
	Subtotal	199
Antidiabetic drugs	Antidiabetic drugs	335
	Subtotal	335
Anticancer drugs	anti-tumor agents	25
	Miscellaneous anti-tumor drugs	6
	Subtotal	31

Classification	Detailed classification	Number of items
Antibiotics	Acting mainly on gram-positive bacteria	7
	Acting mainly on gram-negative bacteria	0
	Acting mainly on gram-positive bacteria, rickettsia, and virus	1
	Acting mainly on fungus, strongylus	1
	Acting mainly on gram- positive/negative bacteria	7
	Miscellaneous antibiotic drugs (including complex antibiotic drugs)	4
	Subtotal	20
Chemo-therapeutics	Furan preparations	0
	Miscellaneous chemotherapeutics	8
	Subtotal	8
Others (classification that does not belong to the above therapeutic class)		110
Total		1992

1.5. Approval of COVID-19 Treatments and Vaccines

In 2021, 1 treatment and 6 vaccines were manufactured for corona virus infection-19 (hereinafter referred to as COVID-19). The treatment was domestically manufactured, and of the 6 vaccines, 2 were domestically manufactured and 4 were imported.

There is 1 ingredient for the COVID-19 treatment and 4 ingredients for the COVID-19 vaccines. 42.9% of COVID-19 treatment and vaccines were manufactured, and 57.1% were imported (see Table 23).

Table 23. Approval Status of COVID-19 Treatments and Vaccines in 2021

(Unit: Number of items)

Category	Total [Number of ingredients]	COVID-19 treatments	COVID-19 vaccines
Total	7 (100.0%) [5 (100.0%)]	1 [1]	6 [4*]
Manufactured	3 (42.9%) [3 (50.0%)]	1 [1]	2 [2]
Imported	4 (57.1%) [4] (50.0%)]	0 [0]	4 [4]

* A total of 4 ingredients were approved in 2021, as 2 manufactured ingredients and 2 imported ingredients are the same.

Table 23-1. Approval Status of COVID-19 Treatments and Vaccines by Year (2020~2021)

Category		2020	2021	Total
COVID-19 treatments	Manufactured Imported	0 (0.0%) 2 (100.0%)	1 (14.3%) 0 (0.0%)	1 (11.1%) 2 (22.2%)
COVID-19 vaccines	Manufactured Imported	0 (0.0%) 0 (0.0%)	2 (28.6%) 4 (57.1%)	2 (22.2%) 4 (44.5%)
Number of items		2(100.0%)	7(100.0%)	9(100.0%)

Since the approval of two COVID-19 treatments in 2020, another treatment was approved in 2021. COVID-19 vaccines were initially approved in 2021 (see Table 23-1).

Table 24. List of COVID-19 Treatment and Vaccine Approvals

No.	Category	Product name	Company	Active ingredient	Efficacy/ Effectiveness	Approval date
1	Imported	Veklury lyophilized powder for IV injection (Remdesivir)	Gilead Science Korea Ltd.	Remdesivir	COVID-19 treatment	2020-07-24
2	Imported	Veklury solution for IV injection (Remdesivir)	Gilead Science Korea Ltd.	Remdesivir	COVID-19 treatment	2020-07-24
3	Manufactured	Regkirona 960mg(Regdanvimab) (Regdanvimab)(monoclonal antibody, genetic recombination)	Celltrion Pharm, Inc.	Regdanvimab	COVID-19 treatment	2021-02-05
4	Manufactured	Vaxzevria solution for injection	AstraZeneca Korea	Recombinant coronavirus spike protein expression adenoviral vector	COVID-19 prevention	2021-02-10
5	Imported	Vaxzevria solution for injection				2021-05-21
6	Imported	Comirnaty Injection(Tozinameran)(SARS CoV-2 mRNA Vaccine)	Pfizer Korea Ltd.	SARS coronavirus-2 spike protein expression messenger ribonucleic acid (Tozinameran)	COVID-19 prevention	2021-03-05
7	Imported	COVID-19 Vaccine Janssen	Janssen Korea Ltd.	Recombinant coronavirus spike protein expression adenoviral vector	COVID-19 prevention	2021-04-07
8	Imported	Moderna COVID-19 vaccine (SARS corona virus-2 mRNA vaccine) → (Product name changed to) SPIKE(SARS corona virus-2 mRNA vaccine)	GC Pharma	SARS coronavirus-2 spike protein expression messenger ribonucleic acid	COVID-19 prevention	2021-05-21
9	Manufactured	SPIKE(SARS corona virus-2 mRNA vaccine)	Moderna Korea Co., Ltd.			2021-12-13

2

Approval Status of Drugs (Chemical Drugs)

2. Approval Status of Drugs (Chemical Drugs)

According to the analysis of the chemical drugs that were approved in 2021 by the review type, it is found that 23 new drugs, 15 orphan drugs, 287 drugs that require data submission (including 7 incrementally modified drugs), and 20 drug substances were approved. Among the drugs that require data submission (280 items, excluding IMD items), those with new compositions had the highest ratio by 48.9% (137 items). They were followed by those with new salt and those with a change in the strength of active ingredients by 32.9% (92 items) and 8.2% (23 items) respectively (see Table 25).

Table 25. Approval Status of Drugs (Chemical drugs) by Review Type in 2021

Type	Review Type			Number of approved items	
1	New drugs (23)	New drugs		22	
2		New orphan drugs		1	
3	Orphan drugs			15	
4	Drugs that require data submission			287	
4-1	Incrementally modified drugs	New composition		7	3
		New route of administration			4
4-2	Drugs that require data submission	New salts or isomers		280	92
4-3		New drug therapeutic class			4
4-4		New composition			137
4-5		Change in strength			23
4-6		New mode of administration/dosage			2
4-7		New dosage form (same route of administration)			22
4-8					
5	Drug substances			20	

In 2021, 23 new drugs were approved (excluding those with post-approval changes such as those that were removed from the orphan drug list), showing a decrease in number from 28 items that were approved in 2020. Among those that were approved in 2021, 19 items (82.6%) were imported. In 2021, 7 incrementally modified drugs were approved, showing similar numbers as in 2020 (6 items). In detail, the following drugs were approved as incrementally modified drugs; drugs with their efficacy/effectiveness recognized and have new compositions (3 items), and drugs that improved their effectiveness and have new dosage forms (4 items) (see Table 30).

In 2021, the approval system underwent the following changes.

The MFDS utilized “PharmTogether”, a communication channel between the public and the MFDS (allows discussions on pending or upcoming issues in the drug approval and review process) to have drug safety information on adverse effects of which causality cannot be ruled out. This allowed them to provide internationally harmonized safety information to the public.

Additionally, an “official communication channel” was piloted in November 2020 to strengthen the responsibility of counseling by reflecting the results of civil service counseling into the approval/reviews during the new drug approval process. In October 2021, this channel began its official operation pursuant to the amendments of the ‘Regulation on Fees for Pharmaceutical Approval, etc.’The applicants may apply to utilize the “official communication channel”when applying for preliminary review or approval, or during the approval process. During the development stage, the existing

“preliminary review system” is utilized and the “preliminary meeting” is established and operated in addition to the “face-to-face meeting”. In the approval and review stage, “face-to-face review system”was introduced and operates the “initiative meeting”, “supplemental meeting” and “additional supplemental meeting”.

The guidelines for the operation of the official communication channel for medical products are available on the Ministry of Food and Drug Safety website (www.mfds.go.kr) at ▶ Regulations/Data ▶ Regulatory Information ▶ Guidelines for Public Officials / Guidelines for Applicants. The Q&A and user manuals are available on the MFDS website (www.mfds.go.kr) at ▶ Regulations/Data ▶ Public Relations Materials ▶ General Public Relations Materials.

The ‘Operational System for Approval and Review Centered on Drug Products’ was introduced in February 2021 to enhance the efficiency of the drug approval process while reinforcing the responsibility and full-cycle safety management of drug product Applicants. The substances can be registered once it is confirmed that the required data pursuant to Article 4 (1) of the ‘Regulations on the Registration of Drug Substances’are submitted. However, the corresponding drug substances will go through a quality review with the drug product approval data at the time of approval (notification) of the drug product.

To help better understand the system, the MFDS prepared the ‘Q&A on the Management Plan for the Operational System for Approval and Review of Drug Products’. It is available on the MFDS official website at ▶ Electronic Civil Petitions ▶ Guidelines for Industries ▶ Guidelines for Public Officials/Guidelines for Applicants.

2.1. Approval Status of New Drugs

The number of new drugs that were approved in 2021 was 23 items (4 manufactured and 19 imported). Compared to 2020, the number decreased by 32.4%. Analyzing the approved new drugs by their therapeutic class, circulatory system drugs (8 items) were approved the most, and was followed by anti-tumor agents (4 items), anti-allergic drugs (3 items), nervous system drugs (2 items), dermatologic drugs (2 items), and digestive system drugs (2 items) (see Table 26 ~ Table 28).

Table 26. Approval Status of Manufactured/ Imported New Drugs (2014~2021) (Chemical drugs)

(Unit: number of items)

	2014	2015	2016	2017	2018	2019	2020	2021
Manufactured	3	6	2	1	2	4	5	4
Imported	38	22	22	20	9	28	29	19
Total	41[1)]	28[2)]	24[3)]	21[4)]	11[5)]	32[6)]	34[7)]	23[8)]
Year-on-year increase,(%)	-	-31.7%	-14.3%	-12.5%	-47.6%	190.9%	6.3%	-32.4%

1) Includes 1 new drug with a post-approval changes (e.g., revocation from the orphan drug list) in 2014: (Revoked from the orphan drug list) Symbenda Inj.

2) Includes 4 new drugs with a post-approval changes (e.g., revocation from the orphan drug list) in 2015:
(Revoked from the orphan drug list) Xtandi Soft Capsule 40 mg, Volibris Tablet 5mg, 10 mg and Zytiga Tablet 250 mg

3) Includes 4 drugs designated as both new drugs and orphan drugs, and 3 new drugs with a post-approval changes (e.g., revocation from the orphan drug list) in 2016:
(New orphan drugs) Tecfidera Cap. 120, 240 mg, Ofev Soft Cap. 100, 150 mg
(Revoked from the orphan drug list) Jakavi Tab. 5, 15, 20 mg

4) Includes 4 new drugs with a post-approval changes (e.g., revocation from the orphan drug list) in 2017:
(Removed from the orphan drug list) Pomalyst Cap. 1, 2, 3, 4 mg

5) Includes 3 items that were approved as both new drugs and orphan drugs in 2018:

(New orphan drugs) Prevymis Injection and Prevymis Tab. 240 mg, 480 mg

6) Includes 1 drug designated as both new drug and orphan drug, and 3 new drugs with a post-approval changes (e.g., revocation from the orphan drug list) in 2019:
(New orphan drug) Cerdelga Cap. 84 mg
(Revoked from the orphan drug list) Cabometyx Tab. 20, 40, 60 mg

7) Includes 6 new drugs with a post-approval changes (e.g., revocation from the orphan drug list) in 2020:
(Revoked from the orphan drug list) Venclexta Tab. 10, 50, 100 mg and Alunbrig Tab. 30, 90, 180 mg

8) Includes 2 new drugs with a post-approval changes (e.g., revocation from the orphan drug list) in 2021:
(New orphan drug) Galafold capsule
(Revoked from the orphan drug list) Calquence Capsule 100mg

Table 27. Approval Status of New Drugs by Detailed Classification (2014~2021) (Chemical drugs)

(Unit: number of items)

	Nervous system	Circulatory system	Respiratory system	Anticoagulants	Antidiabetics	Other metabolic	Chemotherapy	Anti-neoplastic	Antibiotics	Antiallergenics	Sensory organ	Liver disease	Radiological diagnosis	Anti-hormone drugs	Dermatologic drugs	Digestive systems	Drugs for public hygiene	Total
2014	16	1	4	0	8	0	2	5	0	1	2	1	1	0	0	0	0	41
2015	8	2	1	3	2	0	5	4	2	0	0	0	1	0	0	0	0	28
2016	2	6	2	0	0	0	2	9	0	0	0	0	0	3	0	0	0	24
2017	0	3	0	0	0	0	2	9	1	4	0	1	0	0	1	0	0	21
2018	0	1	0	0	2	0	4	0	0	0	0	0	1	0	1	2	0	11
2019	7	0	0	0	0	1	4	12	0	0	3	0	0	0	0	4	1	32
2020	9	3	0	0	0	1	5	13	0	3	0	0	0	0	0	0	0	34
2021	2	8	0	0	0	0	0	4	0	3	1	0	1	0	2	2	0	23

In 2021, 2 nervous system drugs, 3 miscellaneous circulatory system drugs, 5 miscellaneous blood and body fluid drugs, 4 anti-tumor agents, 3 certified therapeutic agents, 2 dermatologic drugs, and 2 digestive system drugs were approved.

The product name, manufacturer, approval date, active ingredient,

efficacy and effectiveness and mechanism of action of each new drugs approved in 2021 are as follows:

'Galafold Capsule (Migalastat HCl)' (Handok Inc., New-drug with a post-approval changes on Jan 28, 2021) is used as a long-term treatment for adolescents (16 years or older) and adults diagnosed with Fabry disease (α-galactosidase A deficiency) with an amenable mutation.

The active ingredient 'Migalastat HCl' is a terminal galactose analogue of GL-3. It binds to α-Gal A, which does not form an appropriate tertiary structure due to high affinity for the active site of wild-type αGal A and a specific mutant form of genotype αGal A known as amenable mutation. It migrates to the lysosome and allows the enzyme to act, preventing the accumulation of glycosphingolipids such as GL-3 (globotriaosylceramide) and lyso GB3 (globotriaosyl sphingosine).

'Byfavo Inj. 50mg (Remimazolam Besylate)' (Hana Pharm, approved on Jan. 7, 2021) is a drug used to induce and maintain general anesthesia. The active ingredient of this drug is 'Remimazolam Besylate', which exhibits anesthetic and sedative effects by acting on the benzodiazepine binding site of the GABA receptor.

'Yuhan Lazertinib Tablet (Lazertinib Mesylate Monohydrate)' (Yuhan Corporation, approved on Jan. 18, 2021) is used to treat patients with EGFR T790M mutation-positive locally advanced or metastatic non-small cell lung cancer previously treated with EGFR-TKI. The active ingredient 'Lazertinib Mesylate Monohydrate' is

a tyrosine kinase inhibitor (EGFR-TKI), an irreversible epidermal growth factor receptor with high mutation selectivity, which works by inhibiting the growth of tumor cells.

‘Vyzulta ophthalmic solution 0.024% (Latanoprostene bunod)’ (Bausch Health Korea Co., Ltd., approved on Feb. 5, 2021) is a drug used to lower intraocular pressure in patients with open-angle glaucoma or ocular hypertension. The active ingredient ‘Latanoprostene bunod’ is a new chemical substance, which is metabolized to LA (latanoprost acid) and NO donor component BDMN (butanediol mononitrate). It reduces intraocular pressure by a dual mechanism of action that includes uveal-scleral aqueous humor release through latanoprost acid (prostaglandin F2-α analog), a selective PGF2-α (FP) receptor agonist, and trabecular sac/Schlem's canal aqueous humor release through trabecular tissue relaxation by nitric oxide (NO) donation.

‘Calquence Capsule (Acalabrutinib)’ (AstraZeneca Korea, approved on Feb. 5, 2021) is used in combination therapy with obinutuzumab in previously untreated chronic lymphocytic leukemia patients aged 65 years or older, or in patients with comorbidities who are under 65 years of age. The active ingredient ‘Acalabrutinib’ is a selective inhibitor of BTK (Bruton tyrosine kinase) that forms a covalent bond with the BTK active site, irreversibly inhibiting BTK activity and inhibiting the proliferation and survival of malignant B cells as a result.

‘Aklief cream 0.005% (Trifarotene)’ (Galderma Korea Co., Ltd.,

approved on Apr. 27, 2021) is used as a topical treatment for moderate acne with comedones, papules, and pustules (face or body). The active ingredient 'Trifarotene' acts on the retinoic acid receptor (RARγ) of keratinocytes, which is effective in acne treatment through comedolytic activity.

'Piqray(alpelisib)' (Novartis Korea, approved on May 13, 2021) is used in a combination therapy with fulvestrant in postmenopausal women and men for hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative, PIK3CA (α-specific class I phosphatidylinositol-3-kinase Phosphatidyl Inositol Kinase) mutation positive-advanced breast cancer when the disease progresses after endocrine-based therapy. The active ingredient 'alpelisib' is a selective inhibitor of PI3K (phosphatidylinositol-3-kinase), an intracellular signal transduction activation enzyme, and suppresses tumor growth by inhibiting intracellular signal transduction through protein phosphorylation.

'Evrenzo tablets(Roxadustat)' (AstraZeneca Korea, approved on Jul. 9, 2021) is an agent to treat symptomatic anemia in patients with chronic kidney disease. The active ingredient 'Roxadustat' is an inhibitor of HIF-proline 4-hydroxylase (HIF-PHs) that promotes red blood cell production.

'FACBC injection(Fluciclovine(18F) solution)' (DuchemBio Co., Ltd., approved on Sep. 17, 2021) is used in adult male patients whether prostate cancer has recurred due to elevation of Prostate-Specific

Antigen (PSA) in blood after being treated for prostate cancer in the past. The active ingredient 'Fluciclovine (18F) solution' is actively transported to prostate cancer cells by amino acid transporters (LAT1 and ASCT2) and is used to diagnose prostate cancer through positron tomography (PET).

'Nerlynx Tablet(Neratinib maleate)' (Bixink Therapeutics Co., Ltd., approved on Oct. 19, 2021) is used alone as an extended adjuvant in patients with hormone receptor-positive, HER2-receptor positive early breast cancer within 1 year of completing trastuzumab-based treatment previously as adjuvant therapy after surgery. The active ingredient 'Neratinib maleate' of this drug irreversibly binds to the intracellular tyrosine kinase domains of HER1, HER2, and HER4 receptors, inhibiting tumor cell proliferation through phosphorylation of proteins involved in cell growth.

'Cibinqo tablet 100mg(Abrocitinib)' (Pfizer Korea Ltd., approved on Nov. 23, 2021) was developed as an agent for treating moderate to severe atopic dermatitis in adults and adolescents 12 years of age or older subject to systemic therapy. The active ingredient 'Abrocitinib' treats inflammation caused by an abnormal immune response in the skin by inhibiting JAK (Janus Kinase, Janus Kinase), which is involved in signal transduction in inflammatory responses.

'Verquvo(Vericiguat(anaplastic))' (Bayer Korea Ltd., approved on Nov. 30, 2021) is used in combination with other heart failure drugs to reduce the risk of death due to cardiovascular disease and

hospitalization due to heart failure in patients with chronic heart failure. The active ingredient ‘Vericiguat (anaplastic)’ increases the intracellular cGMP level by stimulating soluble guanylate cyclase, contributing to improved myocardial function and vascular tone regulation.

‘DYSVAL Capsule 40mg (Valbenazine ditosylate)’ (Mitsubishi Tanabe Pharma Korea Co. Ltd., approved on Nov. 30, 2021) is used to improve symptoms of tardive dyskinesia in adults. The active ingredient ‘Valbenazine ditosylate’ selectively interrupts VMAT2 (vesicular monoamine transporter 2), a transporter that delivers monoamines (such as dopamine, a neurotransmitter), inhibiting monoamine absorption. It reduces the amount of dopamine released from presynaptic neurons, which decreases involuntary movements.

‘OZANEX Cream (Ozenoxacin)’ (Bukwang Pharm. Co., Ltd., approved on Dec. 10, 2021) is effective against Staphylococcus aureus (S. aureus) and Streptococcus pyogenes (S. pyogenes), and is used as a short-term topical treatment of impetigo. The active ingredient ‘Ozenoxacin’ contributes to the antibacterial action by inhibiting the bacterial enzymes, DNA gyrase, and topoisomerase IV.

‘FEXUCLUE Tablet 40mg (Fexuprazan hydrochloride)’ (Daewoong Pharmaceutical Co., Ltd., approved on December 30, 2021) is an agent for treating erosive gastroesophageal reflux disease and a new class of gastric acid secretion inhibitor. The active ingredient ‘Fexuprazan hydrochloride’ is a potassium-competitive acid blocker (P-CAB), and contributes to the inhibition of gastric acid secretion.

Table 28. Approval Status of New Drugs in 2021 (Chemical drugs)

No	Manufactured/ Imported	Product	Company	Date of Approval	Classification	Efficacy/Effectiveness (partially omitted)
1	Imported	Galafold capsule (Migalastat HCl)	Handok Inc.	(Designated as new drug) (2021-01-28) 2017-12-20	Miscellaneous digestive system drugs	Long-term treatment of adolescents aged 16 years or older and adults diagnosed with Fabry disease (α-galactosidase A deficiency) with an amenable mutation
2	Manufactured	Byfavo Inj. 50mg (Remimazolam Besylate)	Hana Pharm Co., Ltd.	2021-01-07	General anesthetics	Induction and maintenance of general anesthesia in adults
3	Manufactured	Yuhan Lazertinib Tablet 80 mg (Lazertinib Mesylate Monohydrate)	Yuhan Corporation	2021-01-18	anti-tumor agents	Treatment of patients with EGFR T790M mutation-positive locally advanced or metastatic non-small cell lung cancer previously treated with EGFR-TKI The efficacy of this drug was based on the response rate and duration of response, and there are no data demonstrating an improvement in survival.
4	Imported	Vyzulta ophthalmic solution 0.024% (Latanoprostene bunod)	Bausch Health Korea Co., Ltd.	2021-02-05	Ophthalmic preparations	Intraocular pressure reduction of the following diseases: Open angle glaucoma, ocular hypertension
5	Imported	Calquence Capsule (Acalabrutinib)	AstraZenaca Korea	(Designated as new drug) (2021-09-10) 2021-02-05	anti-tumor agents	1. Combination or monotherapy with obinutuzumab in previously untreated chronic lymphocytic leukemia patients aged 65 years or older or patients younger than 65 years with comorbidities 2. Monotherapy in patients that have gone through more than one treatment for chronic lymphocytic leukimia
6	Imported	Aklief cream 0.005% (Trifarotene)	Galderma Korea Co., Ltd.	2021-04-27	Emollients (including reagents)	Local treatment of moderate acne with comedones, papules, and pustules in patients that are 9 or older (face or body)
7	Imported	Piqray50mg (Alpelisib), Piqray150mg (Alpelisib), Piqray 200mg (Alpelisib)	Novartis Korea	2021-05-13	anti-tumor agents	Combined administration with fulvestrant in men and postmenopausal women who are hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative, and PIK3CA mutation-positive with breast cancer that is either advanced or metastatic even after endocrine therapy.

No	Manufactured/ Imported	Product	Company	Date of Approval	Classification	Efficacy/Effectiveness (partially omitted)
8	Imported	Evrenzo tablets150mg (Roxadustat)	AstraZeneca Korea	2021-07-09	Miscellaneous blood and body fluid drugs	Treatment of symptomatic anemia in patients with chronic kidney disease
9	Imported	Evrenzo tablets50mg (Roxadustat)				
10	Imported	Evrenzo tablets 100mg (Roxadustat)				
11	Imported	Evrenzo tablets70mg (Roxadustat)				
12	Imported	Evrenzo tablets20mg (Roxadustat)				
13	Manufactured	FACBC injection(Fluciclovine (18F) solution)	DuchemBio Co., Ltd.	2021-09-17	radio-pharmaceutical	Used for positron emission tomography (PET) in the following cases. Confirmation of prostate cancer through the use of Positron tomography(PET) in adult males suspected of recurrence of prostate cancer due to elevation of Prostate-Specific Antigen (PSA) in blood after previous treatment for prostate cancer
14	Imported	Nerlynx Tablet (Neratinib maleate)	Bixink Therapeutics Co., Ltd.	2021-10-19	anti-tumor agents	Administered alone as an extended adjuvant to patients with hormone receptor-positive and HER2-positive early breast cancer within 1 year of completing trastuzumab-based therapy as postoperatively adjuvant therapy previously
15	Imported	Cibinqo tablet 100mg (Abrocitinib)	Pfizer Korea Ltd.	2021-11-23	Certified therapeutic agent (including nonspecific immuno-suppressant)	Treatment of moderate to severe atopic dermatitis in adults and adolescents 12 years of age or older subject to systemic therapy
16	Imported	Cibinqo tablet 200mg (Abrocitinib)				
17	Imported	Cibinqo tablet50mg (Abrocitinib)				
18	Imported	Verquvo 2.5mg (Vericiguat (anaplastic))	Bayer Korea Ltd.	2021-11-30	Miscellaneous circulatory system drugs	Chronic heart failure: Reducing the risk of death from cardiovascular disease and hospitalization for heart failure in symptomatic chronic heart failure patients with a lower left ventricular ejection fraction of less than 45% who have recently been hospitalized for heart failure or received outpatient intravenous diuretics This drug is administered in combination with other heart failure medicines.
19	Imported	Verquvo 5mg (Vericiguat (anaplastic))				
20	Imported	Verquvo 10mg (Vericiguat (anaplastic))				

No	Manufactured/ Imported	Product	Company	Date of Approval	Classification	Efficacy/Effectiveness (partially omitted)
21	Imported	DYSVAL Capsule 40mg (Valbenazine ditosylate)	Mitsubishi Tanabe Pharma Korea Co., Ltd.	2021-11-30	Miscellaneous central nervous system drugs	Improving symptoms of tardive dyskinesia in adults
22	Imported	OZANEX Cream (Ozenoxacin)	Bukwang Pharmaceutical Co., Ltd.	2021-12-10	Suppurative disorder agents	1. Effective on Staphylococcus aureus (S. aureus), Streptococcus pyogenes (S. pyogenes) 2. Indication Short-term topical treatment of impetigo
23	Manufactured	FEXUCLUE Tablet 40mg (Fexuprazan hydrochloride)	Daewoong Pharmaceutical Co., Ltd.	2021-12-30	Peptic ulcer agents	Treatment of erosive gastro-esophageal reflux disease

* Detailed approval information (efficacy/effectiveness, administration/dosage, and precautions for use) is available at http://nedrug.mfds.go.kr.

2.2. Approval Status of Orphan Drugs

As for chemical drugs approved in 2021, there were 15 new orphan drugs (1 manufactured, 14 imported items) (see Table 29).

Analyzing the approved orphan drugs by their therapeutic class, 10 anti-tumor agents, 2 miscellaneous tumor treatments, 1 antidote, 1 anti-tuberculosis drug and 1 miscellaneous central nervous system drug were approved. Among the 12 orphan drug ingredients that were designated in 2020, 10 were newly designated as orphan drugs. These exclude 'Nalfurapine hydrochloride (designated in 2013)' and 'Lutetium oxodotreotide (injection) and L-Lysine hydrochloride/ L-Arginine hydrochloride (used in combination with Lutetium Oxodotreotide) (injection) (designated in 2019)'.

Table 29. Approval Status of Orphan Drugs in 2021 (Chemical drugs)

No.	Manufactured/ Imported	Product	Company	Date of Approval	Class. Code	Efficacy/Effectiveness	Designation Status of Orphan Drugs	
1	Imported	Oncaspar Lyophilization for injection (Pegaspargase)	Servier Korea Co., Ltd.	2021-02-02	Anti-tumor agents	Combination therapy with other anti-tumor agents to treat acute lymphoblastic leukemia (ALL) in pediatric patients 18 years of age or younger and adult patients	No.	282 (Designated in 2020)
							Ingre-dient	Pegaspargase
							Indi-cation	Combination therapy with other anti-tumor agents for treating acute lymphoblastic leukemia
2	Imported	Koselugo capsule 10 mg (Selumetinib hydrogen sulfate)	AstraZeneca Korea	2021-05-28	Miscella-neous antitumor treatments	Treatment for pediatric patients aged 3 years or older with neurofibromatosis type 1 accompanying symptomatic and inoperable plexiform neurofibroma	No.	279 (Designated in 2020)
							Ingre-dient	Selumetinib hydrogen sulfate
3	Imported	Koselugo capsule 25 mg (Selumetinib hydrogen sulfate)					Indi-cation	Treatment for pediatric patients aged 3 years or older with neurofibromatosis type 1 accompanying symptomatic and inoperable plexiform neurofibroma
4	Imported	Lysakare	Novartis Korea	2021-06-17	Antidotes	Reduction of kidney radiation exposure during PRRT (Peptide Receptor Radionuclide Therapy) using lutetium (177Lu) oxodotreotide in adults	No.	262 (Designated in 2019)
							Ingre-dient	Lutetium oxodotreotide (injection) and L-Lysine Hydrochloride/L-Arginine Hydrochloride (injection) used in combination
							Indi-	Treatment of somatostatin

							cation	receptor-positive adult neuro- endocrine tumors of the stomach, intestine and pancreas and reduction of kidney radiation exposure during this treatment (limited to products administered in combination with lutetium oxodotreotide (injection))
5	Imported	Lorviqua 25mg tablet (Lorlatinib)	Pfizer Korea Ltd.	2021-07-29	Anti-tumor agents	Used as monotherapy in adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC) whose disease progressed despite receiving the following therapy - Treated with alectinib or ceritinib as the first-line ALK inhibitor; or - Treated with crizotinib and at least one other ALK inhibitor The efficacy of this drug was based on the response rate and duration of response, and there are no data demonstrating improvement in survival time	No.	268 (Designated in 2020)
							Ingre-dient	Lorlatinib
							Indi-cation	Treatment of patients with ALK-positive non-small cell lung cancer previously treated with anaplastic lymphoma kinase (ALK) inhibitors - Treated with alectinib or ceritinib as the first-line ALK inhibitor; or - Treated with crizotinib and at least one other ALK inhibitor
6	Imported	Lorviqua 100mg tablet (Lorlatinib)	Pfizer Korea Ltd.	2021-07-29				
7	Imported	Xpovio20mg (Selinexor)	DKSH Korea Co., Ltd.	2021-07-29	Anti-tumor agents	1. Combination therapy with dexamethasone in adult patients with relapsed or refractory multiple myeloma who previously received at least two proteasome inhibitors, at least two immunomodulatory imide therapeutics, and at least one anti-CD38 antibody in any of the four therapeutic regimens 2. Treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma after two or more systemic therapies	No.	284 (Designated in 2020)
							Ingre-dient	Selinexor
							Indi-cation	1. Combination therapy with dexamethasone in adult patients with relapsed or refractory multiple myeloma who previously received at least two proteasome inhibitors, at least two immuno-modulatory imide therapeutics, and at least one anti-CD38 antibody in any of the four therapeutic regimens 2. Treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma after two or more systemic therapies
8	Imported	Braftovi 75 mg (Encorafenib)	Ono Pharma Korea Co., Ltd.	2021-08-19	Anti-tumor agents	Combination therapy with cetuximab in treating adult patients with metastatic colorectal cancer with confirmed BRAF V600E mutation who have experience of previous treatment	No.	283 (Designated in 2020)
							Ingre-dient	Encorafenib
							Indi-cation	Combination therapy with cetuximab in treating adult patients with metastatic colorectal cancer with confirmed BRAF V600E mutation who have experience of previous

								treatment
9	Imported	Bukwang Pretomanid tablet 200mg → (Product name changed to) Dovprela tablet 200mg 200mg (Pretomanid)	Bukwang Pharm Co.,Ltd → (Company changed to) Viatris Korea Co., Ltd.	2021-10-15	Anti-tuberculosis agents	○ Effective on Mycobacterium tuberculosis ○ Indication Combination therapy with bedaquiline and linezolid for widespread drug resistant pulmonary tuberculosis and treatment-resistant or non-responsive multidrug resistant pulmonary tuberculosis in adults ○ Limited use The safety and efficacy of this drug are not established for the treatments of latent infection caused by Mycobacterium tuberculosis, drug-sensitive tuberculosis, extra-pulmonary tuberculosis, and non-reactive multidrug resistant tuberculosis, and not for concomitant administration of drugs other than bedaquiline and linezolid	No. Ingre-dient Indi-cation	280 (Designated in 2020) Pretomanid Combination therapy with bedaquiline and linezolid for widespread drug resistant pulmonary tuber-culosis and (XDR-TB) treatment-resistant or non-esponsive multidrug resis-tant pulmonary tuberculosis (TI/NR MDR-TB) in adults
10	Manufactured	REMITCH OD TABLETS 2.5microgram (Nalfurafine hydrochloride	SK Chemicals	2021-10-26	Miscella-neous central nervous system drug	Improvement of pruritus not sufficiently effective with existing treatments in hemodialysis patients	No. Ingre-dient Indi-cation	154 (Designated in 2013) Nalfurafine hydrochloride Improvement of pruritus in hemodialysis patients (limited to cases where existing treatments are not sufficiently effective)
11	Imported	Velexbru tablet 80 mg (Tirabrutinib hydrochloride)	Ono Pharma Korea Co., Ltd.	2021-11-05	Anti-tumor agents	Monotherapy in patients with relapsed or refractory B-cell primary central nervous system lymphoma The efficacy/effectiveness of this drug is approved based on the overall response rate, and there are no clinical trial results to prove clinical benefits such as increased survival time	No. Ingre-dient Indi-cation	276 (Designated in 2020) Tirabrutinib Relapsed or refractory B-cell primary central nervous system lymphoma
12	Imported	Tabrecta Film coated tablet 150mg (Capmatinib)	Novartis Korea	2021-11-23	Anti-tumor agents	Treatment of patients with locally advanced or metastatic non-small cell lung cancer with confirmed MET exon 14 skipping The efficacy of this drug was based on the response rate and duration of response, and there are no data demonstrating improvement in survival time.	No. Ingre-dient	275 (Designated in 2020) Capmatinib
13	Imported	Tabrecta flim-coated tablet 200mg (Capmatinib)					Indi-cation	Non-small cell lung cancer with confirmed MET ex 14 skipping
14	Imported	TEPMETKO film-coated tablet 225mg	Merck Ltd.	2021-11-23	Anti-tumor agents	Treatment of patients with locally advanced or metastatic non-small cell	No. Ingre-dient	267 (Designated in 2020) Tepotinib hydrochloride

		(Tepotinib hydrochloride hydrate)				lung cancer with confirmed MET exon 14 skipping The efficacy of this drug was based on the response rate and duration of response, and there are no data demonstrating improvement in survival time	Indi-cation	Locally advanced or metastatic non-small cell lung cancer with confirmed METex14 skipping alteration
15	Imported	Turalio capsule 200mg (Pexidartinib hydrochloride)	Daiichi-Sankyo Korea Co., Ltd.	2021-12-29	Anti-tumor agents	Treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) in a severely morbid condition or functional limitation that cannot be improved by surgery	No.	270 (Designated in 2020)
							Ingre-dient	Pexidartinib hydrochloride
							Indi-cation	Treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) in a severely morbid condition or functional limitation that cannot be improved by surgery

* Detailed approval information (efficacy/effectiveness, administration/usage, and precautions for use) is available at http://nedrug.mfds.go.kr.

2.3. Approval Status of Incrementally Modified Drugs

“Incrementally modified drugs” refers to drugs that the Minister of Food and Drug Safety designates as incrementally modified or medically advanced in its safety, efficacy and effectiveness (medication compliance, convenience, etc.) compared to the approved (notified) drugs that require data submission pursuant to Article 2(8) of the ‘Regulation for Pharmaceutical Approval, Notification and Reviews’.

The development types of recently approved incrementally modified drugs are as follows: In 2015, development of those with new dosage form was noticeable. From 2016 to 2017, combination drugs with new composition of active substances (drugs containing 2 or more active ingredients in one product) were noticeably developed. In 2018, 6 sustained-release tablet items with improved administration and dosage by reducing the number of intakes were designated as incrementally modified drugs. In 2019, 11 items with improved

efficacy and 2 items with improved effectiveness were approved, totaling to approval of 13 designated incrementally modified drugs. In 2020, 5 items with improved effectiveness, including 4 sustained-release tablet items with improved intake convenience and compliance by a change in dosage form and administration/dosage and 1 item with improved efficacy were approved as incrementally modified drugs. In 2021, 3 new combination drugs with new compositions of active ingredients and 4 items with improved effectiveness through change in the route of administration with new dosage forms were designated as incrementally modified drugs (see Table 30).

The detailed designation criteria for incrementally modified drugs that were approved in 2021 (7 items) are as follows: 3 combination drugs with improved efficacy and effectiveness (medication compliance or convenience) through new composition (hyperlipidemia drug combination 2) and 4 items with improved effectiveness (medication compliance and convenience in administration) through development of a new dosage form (oral → patch).

Table 30. Types of Incrementally Modified Drugs in 2015~2021

Year	New composition or compounding ratio	New dosage form (Same route of administration)	New route of administration	Total
2015	7	11	0	18
2016	22	1	1	24
2017	7	4	0	11
2018	0	6	0	6
2019	13	0	0	13
2020	2	4	0	6
2021	3	0	4	7

The Ministry of Food and Drug Safety has been publishing the 「Casebook of approved incrementally modified drugs」 (Guidance for

applicants) since November 2011. The casebook contains the current status and cases of incrementally modified drugs for the domestic pharmaceutical industries to utilize in drug research and development. The status of incrementally modified drugs approved in 2021 will be reflected in the 「Casebook of approved incrementally modified drugs」 (Guidance for applicants) for 2022, including the approval status, status by product type, detailed designation criteria by case, non-designated cases, etc.

Analyzing the incrementally modified drugs by their designation criteria, drugs with improved efficacy with a proven increase in therapeutic effects (69 items, 55.2%) and those with improved effectiveness through improvement of formulation (47 items, 37.6%) accounted for 92.8% of the total incrementally modified drugs, and those with designation of advancement of pharmaceutical technology and those with improved safety accounted for 5.6% (7 items) and 3.2% (4 items) respectively (Figure 7).

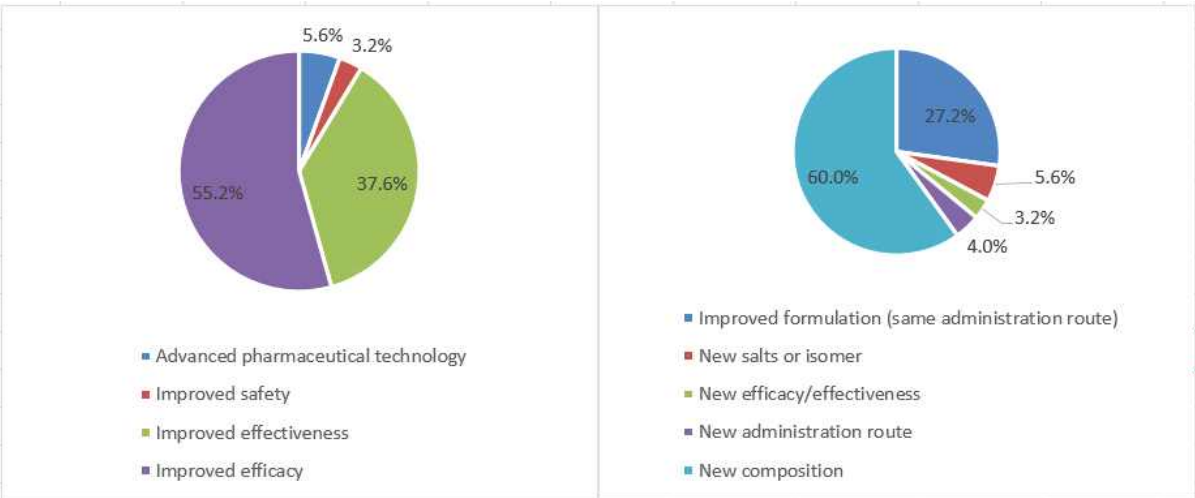

Figure 7. Approval Status of Incrementally Modified Drugs by Designation Criteria and by Type (2009~2021)

Table 31. List of Incrementally Modified Drugs (2009~2021)

No.	Product name	Company	Approval date	Detailed classification	Remarks
1	Amosartan Tab. 5/50mg	Hanmi Pharm. Co., Ltd.	2009-03-31	Antihypertensives	Change of active substance type or compounding ratio
2	Amosartan Tab. 5/100mg				
3	COZAAR XQ Tablet 5/50mg	MSD Korea Co., Ltd. → (transfer) Organon Korea Co., Ltd	2009-11-20		
4	COZAAR XQ Tablet 5/100mg				
5	Potastine OD Tab.	Hanmi Pharm . Co., Ltd.	2010-02-11	Antihistamines	Salt and dosage form changes
6	CLANZA CR Tab. (Aceclofenac)	Korea United Pharm. Inc.	2010-04-14	Antipyretics, analgesics, and antiinflammatory drugs	Change in dosage form, strength and mode of administration/dosage
7	Ridrone plus tablet	Pacific Pharmaceuticals	2010-06-23	Miscellaneous metabolic drugs	Change of active substance type or compounding ratio
8	RISENEX-PLUS Tab.	Celltrion Pharm, Inc.	2010-06-23		
9	RISENPLUS TAB	DAEWOONG PHARMACEUTICAL CO.,LTD.	2010-06-23		
10	Amosartan Tab. 10/50mg	Hanmi Pharm. Co., Ltd.	2010-10-15	Antihypertensives	Change of active substance type or compounding ratio
11	COZAAR XQ Tablet 10/50mg	MSD Korea Co., Ltd. → (transfer) Organon Korea Co., Ltd	2010-10-15		
12	Ultracet ER Tab.	Janssen Korea Ltd.	2010-11-22	Antipyretics, analgesics, and antiinflammatory drugs	Change in dosage form, strength and mode of administration/dosage
13	ROXFEN CR Tablet	SHIN POONG PHARM. CO., LTD.	2011-03-18	Antipyretics, analgesics, and antiinflammatory drugs	Change in dosage form, strength and mode of administration/dosage
14	Pletaal SR Capsules	Korea Otsuka Pharmaceutical	2011-04-19	Miscellaneous blood and body fluid drugs	Change in dosage form, strength and mode of administration/dosage
15	Apetrol ES oral suspension	LG Life Science→ (name change) LG Chem Ltd.	2012-03-27	anti-tumor drugs	Change in strength and mode of administration/dosage
16	Ridonel D Tab.	Hanmi Pharm. Co., Ltd.	2012-04-03	Miscellaneous metabolic drugs	Change in strength and mode of administration/dosage
17	RISENEX-M Tab.	HANLIM PHARM. CO., LTD.	2012-04-03		
18	LETOPRA TAB.20mg	Ahngook Pharm.	2012-06-18	Peptic ulcer drugs	New salts or isomers (first in Korea)

No.	Product name	Company	Approval date	Detailed classification	Remarks
19	Nasaflex Nasal Spray	HANLIM PHARM. CO., LTD.	2012-11-16	Otic and nasal drugs	Change in the type of active substance or compounding ratio
20	Motesoneplus Nasal Spray	Hanmi Pharm. Co., Ltd.	2012-11-16		
21	KanarbPlus Tablet 120/12.5mg	Boryung Pharmaceutical	2013-01-04	Antihypertensives	Change in the type of active substance or compounding ratio
22	KanarbPlus Tablet 60/12.5mg				
23	Olmetan Tab. 22.08mg (olmesartan cilexetil)	JINYANG PHARM CO.,LTD.	2013-01-31	Antihypertensives	New salts or isomers (first in Korea)
24	Olmesin S tab (olmesartan cilexetil)	SK Chemicals			
25	OLMOS-F Tab. 22.08mg (Olmesartan cilexetil)	Ahngook Pharm.			
26	Olmexetil Tablet 22.08mg (Olmesartan cilexetil)	Jeil Pharmaceutical Co., Ltd.			
27	CILOSTAN CR Tab. (Cilostazol)	Korea United Pharm. Inc.	2013-02-28	Miscellaneous blood and body fluid drugs	Change in dosage form, strength or mode of administration/dosage
28	Julian Tab.15mg (Clomipramine HCl)	DongKook Pharmaceutical Co., Ltd.	2013-03-20	Miscellaneous urogenital and anal organ drugs	Added an evidentally different efficacy/effectiveness
29	Nenoma Tablet 15mg (Clomipramine HCl)	Huons Co., Ltd.			
30	Condencia Tab. 15mg (Clomipramine HCl)	CTCBIO INC.			
31	Clojac Tab. (Domipramine hydrochloride)	JINYANG PHARM CO.,LTD.			
32	VOGMET Tablet 0.2/250mg	CJ Cheiljedang Corp. → (name change)HK inno.N	2013-06-17	Antidiabetics	Change in the type of active substance or compounding ratio
33	VOGMET Tablet 0.2/500mg				
34	Bonviva Plus Tablet	Dreampharma Corp. → (name change) Alvogen Korea Co., Ltd.	2013-07-08	Miscellaneous metabolic drugs	Change in the type of active substance or compounding ratio
35	Levacalm Tab. 20/160mg	LG Life Science→ (name change) LG Chem Ltd.	2013-07-25	Antihypertensives	Change in the type of active substance or compounding ratio
36	Levacalm Tab. 10/160mg				
37	Levacalm Tab. 10/80mg				
38	Zemimet SR Tab. 25/500mg	LG Life Science→ (name change) LG Chem Ltd.	2013-07-25	Antidiabetics	Change in the type of active substance or compounding ratio
39	Dexid Tab 480mg (r-thioctic acid tromethamine)	Bukang Pharm Co.,Ltd	2013-11-21	Miscellaneous metabolic drugs	New salts or isomers (first in Korea)
40	Zemimet SR Tab. 50/1000mg	LG Life Science→ (name change) LG Chem Ltd.	2014-11-07	Antidiabetics	Change in the type of active substance or compounding ratio

No.	Product name	Company	Approval date	Detailed classification	Remarks
41	Sapodifil SR Tablet 300mg (Sarpogrelate hydrochloride)	Alvogen Korea Co., Ltd.	2015-01-23	Miscellaneous blood and body fluid drugs	Change in dosage form, strength and mode of administration/dosage
42	Anpran SR Tablet 300mg (Sapogrelate hydrochloride)	Jeil Pharmaceutical Co., Ltd.			
43	Anpla X-SR Tab 300mg (Sapogrelate hydrochloride)	SK Chemicals			
44	ANPL-ONE SR Tab. 300mg (Sapogrelate hydrochloride)	DAEWOONG PHARMACEUTICAL CO.,LTD.			
45	ANFRADE SR Tablet 300mg (Sarpogrelate hydrochloride)	CJ Healthcare Corp. → (name change)HK inno.N			
46	Pelubi CR Tab. (Pelubiprofen)	Daewon Pharm. Co., Ltd	2015-03-13	Antipyretics, analgesics, and antiinflammatory drugs	Change in dosage form, strength and mode of administration/dosage
47	Tenelia M SR tab. 10/750mg	Handok Inc.	2015-03-31	Antidiabetics	Change in the type of active substance or compounding ratio
48	Tenelia M SR tab. 20/1000mg				
49	Tenelia M SR tab. 10/500mg				
50	EXON SR TABLET (Eperisone hydrochloride)	AJU PHARM CO., LTD.	2015-03-31	Skeletal muscle relaxants	Change in dosage form, strength and mode of administration/dosage
51	Exonin CR tab (Eperisone hydrochloride)	SK Chemicals			
52	Epesine SR Tab. (Eperisone hydrochloride)	Myungmoon Pharm. Co., Ltd.			
53	Nerexone SR Tab. (Eperisone HCl)	Daewon Pharm. Co., Ltd			
54	Eperinal SR Tablet (Eperisone hydrochloride)	Jeil Pharmaceutical Co., Ltd.			
55	Zemimet SR Tab. 50/500mg	LG Life Science→ (name change) LG Chem Ltd.	2015-10-12	Antidiabetics	Change in the type of active substance or compounding ratio
56	Sugamet XR Tablet 2.5/500 mg	DONG-A ST	2015-12-31	Antidiabetics	Change of active substance type or compounding ratio
57	Sugamet XR Tablet 2.5/850 mg				
58	Sugamet XR Tablet 5/1000 mg				
59	Dukarb Tablet 30/5mg	Boryung Pharmaceutical	2016-05-30	Antihypertensives	Change in the type of active substance or compounding ratio
60	Dukarb Tablet 30/10mg				
61	Dukarb Tablet 60/5mg				
62	Dukarb Tablet 60/10mg				

No.	Product name	Company	Approval date	Detailed classification	Remarks
63	Karbpine Tab. 60/5mg	Boryung Biopharma Co., Ltd.	2016-05-31	Antihypertensives	Change in the type of active substance or compounding ratio
64	Karbpine Tab. 60/10mg				
65	Karbpine Tab. 30/5mg				
66	Karbpine Tab. 30/10mg				
67	CANDE AMLO Tablet 16/10mg	SHIN POONG PHARM. CO., LTD.	2016-06-24	Antihypertensives	Change in the type of active substance or compounding ratio
68	CANDE AMLO Tablet 16/5mg				
69	CANDE AMLO Tablet 8/5mg				
70	MACHKHAN Tablet 8/5mg	CJ Healthcare Corp. → (name change)HK inno.N	2016-06-24	Antihypertensives	Change in the type of active substance or compounding ratio
71	MACHKHAN Tablet 16/10mg				
72	MACHKHAN Tablet 16/5mg				
73	Duvimet XR Tab. 0.25/750mg	Chong Kun Dang Pharm.	2016-06-30	Antidiabetics	Change in the type of active substance or compounding ratio
74	Duvimet XR Tab. 0.25/1000mg				
75	Duvimet XR Tab. 0.5/1000mg				
76	GASTIIN CR Tab. (Mosapride citrate dihydrate)	Korea United Pharm. Inc.	2016-06-30	Miscellaneous digestive system drugs	Change in dosage form, strength and mode of administration/dosage
77	Zemimet SR Tab. 25/1000mg	LG Life Science→ (name change) LG Chem Ltd.	2016-06-30	Antidiabetics	Change in the type of active substance or compounding ratio
78	Duvimet XR Tab. 0.25/500mg	Chong Kun Dang Pharm.	2016-09-01	Antidiabetics	Change in the type of active substance or compounding ratio
79	LIPORAXEL SOLUTION (PACLITAXEL)	DAEHWA PHARMACEUTICAL., LTD.	2016-09-09	anti-tumor drugs	New route of administration
80	Safrep Solution	CTCBIO INC.	2016-10-06	X-ray contrast agent	Change in the type of active substance or compounding ratio
81	Duocolon Solution	Alvogen Korea Co., Ltd.	2016-10-06	X-ray contrast agent	Change in the type of active substance or compounding ratio
82	Coolipa Sol.	Ahngook Pharm.	2016-10-06	X-ray contrast agent	Change in the type of active substance or compounding ratio
83	Surfolase CR Tablet (Acebrophylline)	Hyundai Pharm	2017-02-24	Miscellaneous respiratory organ drugs	Change in dosage form, strength and mode of administration/dosage
84	LEVOTICS CR Tab. (Levodropropizine)	Korea United Pharm. Inc.	2017-04-12	Antitussive expectorants	Change in dosage form, strength and mode of administration/dosage
85	Levocare CR Tablets (Levodropropizine)	Kwangdong Pharm, Ltd.	2017-04-12	Antitussive expectorants	Change in dosage form, strength and mode of administration/dosage
86	Neotuss SR Tab. (Levodropropizine)	JW shinyak	2017-04-12	Antitussive expectorants	Change in dosage form, strength and mode of administration/dosage
87	Amosartan Plus Tab. 5/50/12.5mg	Hanmi Pharm. Co., Ltd.	2017-06-29	Antihypertensives	Change in the type of active substance or compounding ratio
88	Amosartan Plus Tab. 5/100/12.5mg				
89	Amosartan Plus Tab. 5/100/25mg				

No.	Product name	Company	Approval date	Detailed classification	Remarks
90	TWOTOPSPLUS Tab. 40/5/12.5 mg	ILDONG PHARMACEUTICAL CO., LTD.	2017-07-25	Antihypertensives	Change in the type of active substance or compounding ratio
91	TWOTOPSPLUS Tab. 80/5/12.5 mg				
92	TWOTOPSPLUS Tab. 80/10/12.5 mg				
93	TWOTOPSPLUS Tab. 80/10/25 mg				
94	BELION CR Tab. (Bepotastine salicylate)	HANLIM PHARM. CO., LTD.	2018-07-30	Antihistamines	Change in dosage form, strength and mode of administration/dosage
95	Tari-S CR tab. (Bepotastine salicylate)	Sam Chun Dang Pharm. Co.,Ltd.			
96	Beposta SR Tab. (Bepotastine salicylate)	Daewon Pharm. Co., Ltd			
97	Bepo-Q SR Tab. (Bepotastine salicylate)	Kwangdong Pharm, Ltd.			
98	Bepotan SR Tab. (Bepotastine salicylate)	DongKook Pharmaceutical Co., Ltd.			
99	Beporine SR Tab. (Bepotastine salicylate)	SAM-A PHARM. CO., LTD.			
100	CLEANVIEWAL Powder	Taejoon Pharmaceutical Co., Ltd.	2019-01-31	X-ray contrast agent	Change in the type of active substance or compounding ratio
101	STAFEN Cap.	HANLIM PHARM. CO., LTD.	2019-04-03	Antiarterioscler-otic agents	Change in the type of active substance or compounding ratio
102	Neustatin-Duo Capsule	Samjin Pharmaceutical Co., Ltd.	2019-04-03	Antiarterioscler-otic agents	Change in the type of active substance or compounding ratio
103	Pitalone-F Cap.	DongKook Pharmaceutical Co., Ltd.	2019-04-03	Antiarterioscler-otic agents	Change in the type of active substance or compounding ratio
104	Pevaro-F Cap.	Ahngook Pharm.	2019-04-03	Antiarterioscler-otic agents	Change in the type of active substance or compounding ratio
105	Liloufen Cap.	GL Pharma	2019-04-03	Antiarterioscler-otic agents	Change in the type of active substance or compounding ratio
106	Uptava Cap.	Daewon Pharm. Co., Ltd	2019-04-03	Antiarterioscler-otic agents	Change in the type of active substance or compounding ratio
107	Lipestin Cap.	Korea Prime Pharm. Co., Ltd.	2019-04-03	Antiarterioscler-otic agents	Change in the type of active substance or compounding ratio
108	PF Capsule.	Dong Kwang Pharm. Co.,Ltd.	2019-04-03	Antiarterioscler-otic agents	Change in the type of active substance or compounding ratio
109	Orafang Tab.	Pharmbio Korea Inc.	2019-04-11	X-ray contrast agent	Change in the type of active substance or compounding ratio
110	True Set Tablet 40/5/12.5mg	Yuhan Corporation	2019-08-23	Antihypertensives	Change in the type of active substance or compounding ratio
111	True Set Tablet 80/5/12.5mg				
112	True Set Tablet 80/5/25mg				
113	OnePrep 1.38 powder	Kungang Pharmaceuticals	2020-04-10	X-ray contrast agent	Change in the type of active substance or compounding ratio
114	Codaewon S syrup	Daewon Pharm. Co., Ltd	2020-07-15	Antitussive expectorants	Change in the type of active substance or compounding ratio

No.	Product name	Company	Approval date	Detailed classification	Remarks
115	Recomid SR tablet(Rebamipide)	Yuhan Corporation	2020-12-16	Peptic ulcer drugs	Change in dosage form, strength and mode of administration/dosage
116	Mucotect SR Tab.	GC Pharma	2020-12-16	Peptic ulcer drugs	Change in dosage form, strength and mode of administration/dosage
117	MUCOTRA SR tab	DAEWOONG PHARMACEUTICAL CO.,LTD.	2020-12-16	Peptic ulcer drugs	Change in dosage form, strength and mode of administration/dosage
118	Bidreba SR 150mg	Daewon Pharm. Co., Ltd	2020-12-16	Peptic ulcer drugs	Change in dosage form, strength and mode of administration/dosage
119	Atromega combigel soft capsule	Korea United Pharm Inc.	2021-01-21	Antiarteriosclerotic agents	Change in the type of active substance or compounding ratio
120	LivaloZet Tablet 2/ 10mg	JW Pharmaceutical	2021-07-28	Antiarteriosclerotic agents	Change in the type of active substance or compounding ratio
121	LivaloZet Tablet 2/ 10mg				
122	Donerion Patch 87.5mg (Donepezil)	Celltrion Pharm, Inc.	2021-11-05	Miscellaneous central nervous system drugs	New route of administration
123	Donerion Patch 175mg (Donepezil)				
124	Donhesive Patch 87.5mg (Donepezil)	ICURE Pharmaceutical Inc.	2021-11-05	Miscellaneous central nervous system drugs	New route of administration
125	Donhesive Patch 175mg (Donepezil)				

* Detailed approval information (efficacy/effectiveness, administration/dosage, and precautions for use) is available at http://nedrug.mfds.go.kr.

2.4. Approval Status of Drugs that Require Data Submission

Drugs that require data submission refer to drugs that are not new drugs, but require safety and efficacy review, such as ▲Drugs that contain new salts (isomers) as an active substance, ▲Drugs belonging to new efficacy groups, ▲New composition of active substances, or changes only in strength, ▲Drugs with new administration routes, ▲Drugs with new administration/ dosage, ▲New dosage form (same administration route), etc.

Among the drugs that require data submission (excluding 7 incrementally modified drug items) that were approved in 2021, the development of drugs with a new composition or changes in strength accounted for the largest portion (57.1%, 160 items), followed by drugs with new salts or isomers (32.9%, 92 items) (see Table 30).

Table 32. Approval Status of Drugs that require Data Submission in 2021

Review type of drugs that require data submission		Number of approved items	
New salts or isomers		92	
New efficacy group		4	
New composition of active substance or change only in strength	160	New composition	137
		Change in strength	23
New route of administration		0	
New mode of administration/dosage		2	
New dosage form (same route of administration)		22	
Total		280	

* Excluding incrementally modified drugs (drugs that require data submission)

1) New salt or isomer drugs (92 items)

92 manufactured chemical drugs were approved with new salts or as new isomers. Of those, 51 items were approved with new salts for a previously approved antidiabetics, Dapagliflozin propanediol hydrate, accounting for the majority by 55.4%. 10 items (10.9%) were drugs where Teneligliptin hydrobromide hydrate was changed to Teneligliptin ditosylate dihydrate, 8 Vildagliptin items(8.7%) were developed with new salt, 8 items (8.7%) were developed from Empagliflozin to Empagliflozin L-proline, and 6 items (6.5%) were drugs where Sitagliptin phosphate hydrate was changed into Sitagliptin hydrochloride hydrate. There was a combination drug (1.1%) developed with Dapaliflozinpropanediol and Sitagliptin phosphate hydrate that were approved with new salts. As a result, the antidiabetics accounted for the majority of the new salt or isomer drugs approved in 2021 (84 items, 91.3%). Other approved drugs include: hypertension treatment Amlodipine besylate developed with new salts in 4 items; acute coronary syndrome treatment developed with Ticagrelor nafadisylate dihydrate instead of Ticagrelor in 2 items; one item with new salt of antipyretic analgesic Felubiprofene changed into Felubiprofentromethanmine; and arthritis treatment Tofacitinib citrate developed as Tofacitinib in one item (see Table 33).

Table 33. Approval Status of Drugs with New Salt or as New Isomer that require Data Submission in 2021

No.	Manufac-tured/ Imported	Product name	Company	Approval date	Detailed classification	Efficacy/Effectiveness (partially summarized)	Remarks
1	Manufac-tured	CKDticagrelor Tablet 90mg	Chong Kun Dang Pharm.	2021-01-26	Antiarteriosclerotic agents	Combination therapy to reduce the incidence of myocardial infarction and stroke, death due to cardiovascular events, thrombotic cardiovascular events	Naphthalenedisulfonate dihydrate
2	Manufac-tured	CKDticagrelor Tablet 60mg					
3	Manufac-tured	Dapacell Tab. 5mg (Dapagliflozin anhydrous lactose mixture)	Celltrion Pharm, Inc.	2021-02-04	Antidiabetics	Adjuvant drug for diet therapy in type 2 diabetes patients	Propanediol → Anhydrous lactose mixture
4	Manufac-tured	Dapacell Tab. 10mg (Dapagliflozin anhydrous lactose mixture)					
5	Manufac-tured	Vildagle Tab.50mg (Vildagliptin HC)	Hanmi Pharm. Co., Ltd.	2021-02-10	Antidiabetics	Adjuvant drug for diet therapy in type 2 diabetes patients	Hydrochloride
6	Manufac-tured	CKD Tofacitinib Tab. 5mg	Chong Kun Dang Pharm.	2021-03-26	Certified therapeutic agent(including nonspecific immunosuppressant)	Rheumatoid arthritis, psoriatic arthritis	Tofacitinib citrate → Tofacitinib
7	Manufac-tured	Tenelican Tab. 20mg (Teneligliptin ditosylate dihydrate)	Dongkook Pharmaceutical Co., Ltd.	2021-04-01	Antidiabetics	Adjuvant drug for diet therapy in type 2 diabetes patients	Hydrobromide hydrate → Ditosylate dihydrate
8	Manufac-tured	Tenerotin Tab. (Teneligliptin ditosylatedihydrate)	KMS Pharm Co., Ltd.	2021-04-01	Antidiabetics	Adjuvant drug for diet therapy in type 2 diabetes patients	Hydrobromide hydrate → ditosylatedihydrate
9	Manufac-tured	Telium Tablet 20mg (Teneligliptin ditosylatedihydrate)	Hana pharm	2021-04-01	Antidiabetics	Adjuvant drug for diet therapy in type 2 diabetes patients	Hydrobromide hydrate → ditosylatedihydrate
10	Manufac-tured	Teneliel Tab. 20mg (Teneligliptin ditosylatedihydrate)	GL Pharma	2021-04-01	Antidiabetics	Adjuvant drug for diet therapy in type 2 diabetes patients	Hydrobromide hydrate → ditosylatedihydrate
11	Manufac-tured	YUNGJIN Teneligliptin Tab. 20mg(Teneligliptin ditosylate dihydrate)	Yungjin Pharm.	2021-04-01	Antidiabetics	Adjuvant drug for diet therapy in type 2 diabetes patients	Hydrobromide hydrate → Ditosylate dihydrate
12	Manufac-tured	DAEWOONGBIO Teneligliptin TAB. 20mg (Teneligliptin ditosylate dihydrate)	Daewoong Bio Inc.	2021-04-01	Antidiabetics	Adjuvant drug for diet therapy in type 2 diabetes patients	Hydrobromide hydrate → Ditosylate dihydrate

No.	Manufac-tured/ Imported	Product name	Company	Approval date	Detailed classification	Efficacy/Effectiveness (partially summarized)	Remarks
13	Manufac-tured	Tenegli tablet 20mg(Teneligliptin ditosylate d F hydrate)	GENUONE Sciences Inc.	2021-04-01	Antidiabetics	Adjuvant drug for diet therapy in type 2 diabetes patients	Hydrobromide hydrate → Ditosylate dihydrate
14	Manufac-tured	Telia Tablet 20mg (Teneligliptin ditosylatedihydrate)	Guju Pharm. Co., Ltd.	2021-04-01	Antidiabetics	Adjuvant drug for diet therapy in type 2 diabetes patients	Hydrobromide hydrate → ditosylatedihydrate
15	Manufac-tured	Tenellitak Tab. 20mg (Teneligliptin ditosylatedihydrate)	LitePharmTech	2021-04-01	Antidiabetics	Adjuvant drug for diet therapy in type 2 diabetes patients	Hydrobromide hydrate → ditosylatedihydrate
16	Manufac-tured	PELUBI S TAB (Pelubiprofen tromethamine)	Daewon Pharm. Co., Ltd	2021-05-20	Antipyretics, analgesics, and anti-inflammatory drugs	Osteoarthritis Rheumatoid arthritis Lumbodynia relieving Antipyretic of acute upper respiratory tract infection	Tromethamine
17	Manufac-tured	LODIENT 40/ 2.5mg	Hanlim Pharm. Co., Ltd.	2021-05-31	Antihypertensives	Essential hypertension	Amlodipine besylate → S-amlodipine nicotinat
18	Manufac-tured	LODIENT 40/ 5mg					
19	Manufac-tured	LODIENT 80/ 2.5mg					
20	Manufac-tured	LODIENT 80/ 5mg					
21	Manufac-tured	Vildaglmet Tab. 50/500mg	Hanmi Pharm. Co., Ltd.	2021-07-13	Antidiabetics	Adjuvant drug for diet therapy in type 2 diabetes patients	Vildagliptinhydrochloride
22	Manufac-tured	Vildaglmet Tab. 50/850mg					
23	Manufac-tured	Vildaglmet Tab. 50/1000mg					
24	Manufac-tured	Vilda tab 50mg (Vildagliptin Nitrate)	Kyongbo pharma	2021-09-10	Antidiabetics	Adjuvant drug for diet therapy in type 2 diabetes patients	Nitrate
25	Manufac-tured	Duo Rich XR tab. 5/1000mg	Richwood Trading Company Ltd.	2021-10-08	Antidiabetics	Adjuvant drug for diet therapy in type 2 diabetes patients	Dapagliflozin Propanediol hydrate → Dapagliflozin citric acid
26	Manufac-tured	Duo Rich XR tab. 10/1000mg					
27	Manufac-tured	Dapa N Duo XR Tablet 5/1000mg	HK inno.N	2021-10-08	Antidiabetics	Adjuvant drug for diet therapy in type 2 diabetes patients	Dapagliflozin Propanediol hydrate → Dapagliflozin citric acid
28	Manufac-tured	Dapa N Duo XR Tablet 10/1000mg					
29	Manufac-tured	Forglimet XR 5/1000mg	Korea Prime Pharm. Co., Ltd.	2021-10-08	Antidiabetics	Adjuvant drug for diet therapy in type 2 diabetes patients	Dapagliflozin Propanediol hydrate → Dapagliflozin citric acid
30	Manufac-tured	Forglimet XR 10/1000mg					

No.	Manufac-tured/ Imported	Product name	Company	Approval date	Detailed classification	Efficacy/Effectiveness (partially summarized)	Remarks
31	Manufac-tured	DapaminM SR Tab. 5/1000mg	Mother's Pharmaceutical Co., Ltd.	2021-10-12	Antidiabetics	Adjuvant drug for diet therapy in type 2 diabetes patients	Dapagliflozin Propanediol hydrate → Dapagliflozin citric acid
32	Manufac-tured	DapaminM SR Tab. 10/1000mg					
33	Manufac-tured	DapaM XR tab. 10/1000mg	KS Pharm. Inc.	2021-10-12	Antidiabetics	Adjuvant drug for diet therapy in type 2 diabetes patients	Dapagliflozin Propanediol hydrate → Dapagliflozin citric acid
34	Manufac-tured	Daglomet XR Tablet 10/1000mg	Korea Arlico Pharm Co., Ltd.	2021-10-12	Antidiabetics	Adjuvant drug for diet therapy in type 2 diabetes patients	Dapagliflozin Propanediol hydrate → Dapagliflozin citric acid
35	Manufac-tured	Dapa M Tab. 5/1000mg	Aprogen Pharmaceuticals, Inc.	2021-10-12	Antidiabetics	Adjuvant drug for diet therapy in type 2 diabetes patients	Dapagliflozin Propanediol hydrate → Dapagliflozin citric acid
36	Manufac-tured	Dapa M Tab. 10/1000mg					
37	Manufac-tured	Formetaduo SR tab. 10/1000mg	Youngil Pharm. Co., Ltd.	2021-10-12	Antidiabetics	Adjuvant drug for diet therapy in type 2 diabetes patients	Dapagliflozin Propanediol hydrate → Dapagliflozin citric acid
38	Manufac-tured	Ilyang Dapame XR Tab. 5/1000mg	Il-Yang Pharmaceutical Co., Ltd.	2021-10-12	Antidiabetics	Adjuvant drug for diet therapy in type 2 diabetes patients	Dapagliflozin Propanediol hydrate → Dapagliflozin citric acid
39	Manufac-tured	Ilyang Dapame XR Tab. 10/1000mg					
40	Manufac-tured	Damet XR Tab. 5/1000mg	BINEX Co., Ltd.	2021-10-13	Antidiabetics	Adjuvant drug for diet therapy in type 2 diabetes patients	Dapagliflozin Propanediol hydrate → Dapagliflozin citric acid
41	Manufac-tured	Damet XR Tab. 10/1000mg					
42	Manufac-tured	Forximet XR tab. 5/1000mg	Withus Pharmaceutical Co., Ltd.	2021-10-20	Antidiabetics	Adjuvant drug for diet therapy in type 2 diabetes patients	Dapagliflozin Propanediol hydrate → Dapagliflozin citric acid
43	Manufac-tured	Forximet XR tab. 10/1000mg					
44	Manufac-tured	Sugatrolduo XR Tab. 5/1000mg	Saehan Pharmaceutical. Co., Ltd.	2021-10-21	Antidiabetics	Adjuvant drug for diet therapy in type 2 diabetes patients	Dapagliflozin Propanediol hydrate → Dapagliflozin citric acid
45	Manufac-tured	Sugatrolduo XR Tab. 10/1000mg					

No.	Manufac-tured/ Imported	Product name	Company	Approval date	Detailed classification	Efficacy/Effectiveness (partially summarized)	Remarks
46	Manufac-tured	Fosugarduo XR Tab. 5/1000mg	GENUONE Sciences Inc.	2021-10-26	Antidiabetics	Adjuvant drug for diet therapy in type 2 diabetes patients	Dapagliflozin Propanediol hydrate → Dapagliflozin citric acid
47	Manufac-tured	Fosugarduo XR Tab. 10/1000mg					
48	Manufac-tured	CKD Empagliflozin Tab. 10mg(Empagliflozin L-proline)	Chong Kun Dang Pharm.	2021-10-27	Antidiabetics	Adjuvant drug for diet therapy in type 2 diabetes patients	Empagliflozin → Empagliflozin L-proline
49	Manufac-tured	CKD Empagliflozin Tab. 25mg(Empagliflozin L-proline)					
50	Manufac-tured	GludapaduoSR Tablet 5/1000mg	Hanall Biopharma	2021-10-29	Antidiabetics	Adjuvant drug for diet therapy in type 2 diabetes patients	Dapagliflozin Propanediol hydrate → Dapagliflozin citric acid
51	Manufac-tured	GludapaduoSR Tablet 10/1000mg					
52	Manufac-tured	ForxiDM SR Tab. 5/1000mg	Kukje Pharma Co., Ltd.	2021-10-29	Antidiabetics	Adjuvant drug for diet therapy in type 2 diabetes patients	Dapagliflozin Propanediol hydrate → Dapagliflozin citric acid
53	Manufac-tured	ForxiDM SR Tab. 10/1000mg					
54	Manufac-tured	FlogaDuo SR Tab. 5/1000mg	Nexpharm Korea Co., Ltd.	2021-10-29	Antidiabetics	Adjuvant drug for diet therapy in type 2 diabetes patients	Dapagliflozin Propanediol hydrate → Dapagliflozin citric acid
55	Manufac-tured	FlogaDuo SR Tab. 10/1000mg					
56	Manufac-tured	Daglomet XR Tablet 5/1000mg	Korea Arlico Pharm Co., Ltd.	2021-10-29	Antidiabetics	Adjuvant drug for diet therapy in type 2 diabetes patients	Dapagliflozin Propanediol hydrate → Dapagliflozin citric acid
57	Manufac-tured	DapaM XR tab. 5/1000mg	KS Pharm. Inc.	2021-10-29	Antidiabetics	Adjuvant drug for diet therapy in type 2 diabetes patients	Dapagliflozin Propanediol hydrate → Dapagliflozin citric acid
58	Manufac-tured	Jeil teneligliptin Tab. 20mg (teneligliptin ditosylatedihydrate)	Jeil Pharmaceutical Co., Ltd.	2021-11-03	Antidiabetics	Adjuvant drug for diet therapy in type 2 diabetes patients	Hydrobromide hydrate → Ditosylate dihydrate
59	Manufac-tured	Shinpoong Dapa Plus XR Tab. 5/1000mg	Shin Poong Pharm. Co., Ltd.	2021-11-09	Antidiabetics	Adjuvant drug for diet therapy in type 2 diabetes patients	Dapagliflozin Propanediol hydrate → Dapagliflozin citric acid
60	Manufac-tured	Shinpoong Dapa Plus XR Tab.10/1000mg					

No.	Manufac-tured/ Imported	Product name	Company	Approval date	Detailed classification	Efficacy/Effectiveness (partially summarized)	Remarks
61	Manufac-tured	FORSIDAPA M XR Tab. 5/1000mg	Daewoong Bio Inc.	2021-11-10	Antidiabetics	Adjuvant drug for diet therapy in type 2 diabetes patients	Dapagliflozin Propanediol hydrate → Dapagliflozin citric acid
62	Manufac-tured	FORSIDAPA M XR Tab. 10/1000mg					
63	Manufac-tured	Xigdu-L XR Tab. 5/1000mg	GL Pharma Co., Ltd.	2021-11-10	Antidiabetics	Adjuvant drug for diet therapy in type 2 diabetes patients	Dapagliflozin Propanediol hydrate → Dapagliflozin citric acid
64	Manufac-tured	Xigdu-L XR Tab. 10/1000mg					
65	Manufac-tured	CKD Empagliflozin/Metformin Tab. 5/500mg	Chong Kun Dang Pharm.	2021-11-15	Antidiabetics	Adjuvant drug for diet therapy in type 2 diabetes patients	Empagliflozin → Empagliflozin L-proline
66	Manufac-tured	CKD Empagliflozin/Metformin Tab. 5/850mg					
67	Manufac-tured	CKD Empagliflozin/Metformin Tab. 5/1000mg					
68	Manufac-tured	CKD Empagliflozin/Metformin Tab. 12.5/500mg					
69	Manufac-tured	CKD Empagliflozin/Metformin Tab. 12.5/850mg					
70	Manufac-tured	CKD Empagliflozin/Metformin Tab. 12.5/1000mg					
71	Manufac-tured	CKD Empagliflozin/Metformin Tab. 10/500mg					Dapagliflozin Propanediol hydrate → Dapagliflozin
72	Manufac-tured	CKD Empagliflozin/Metformin Tab. 5/500mg					
73	Manufac-tured	CKD Empagliflozin/Metformin Tab. 5/1000mg					
74	Manufac-tured	CKD Empagliflozin/Metformin Tab. 10/1000mg					

No.	Manufac-tured/ Imported	Product name	Company	Approval date	Detailed classification	Efficacy/Effectiveness (partially summarized)	Remarks
75	Manufac-tured	Vildamet tab 50/500mg	Kyongbo pharma	2021-11-30	Antidiabetics	Adjuvant drug for diet therapy in type 2 diabetes patients	Vildagliptin → Vildagliptin Nitrate
76	Manufac-tured	Vildamet tab 50/850mg					
77	Manufac-tured	Vildamet tab 50/1000mg					
78	Manufac-tured	Dapacombi Tab. 10/100mg	Daewon Pharm. Co., Ltd	2021-12-21	Antidiabetics	Adjuvant drug for diet therapy in type 2 diabetes patients	Sitagliptin phosphate hydrate → Sitagliptin Hydrochloride hydrate Dapagliflozin Propanediol hydrate → Dapagliflozin citric acid
79	Manufac-tured	Dapamet SR Tab. 10/500mg	Kyung Dong Pharm. Co., Ltd.	2021-12-23	Antidiabetics	Adjuvant drug for diet therapy in type 2 diabetes patients	Dapagliflozin Propanediol hydrate → Dapagliflozin BisL-prolin
80	Manufac-tured	Dapamet SR Tab. 10/1000mg					
81	Manufac-tured	JeforgaDuo SR Tablet 10/500mg	Jeil Pharmaceutical Co., Ltd.	2021-12-23	Antidiabetics	Adjuvant drug for diet therapy in type 2 diabetes patients	Dapagliflozin Propanediol hydrate → Dapagliflozin BisL-prolin
82	Manufac-tured	JeforgaDuo SR Tablet10/1000mg					
83	Manufac-tured	DM-Cure XR Tablet 10/500mg	Boryung Co., Ltd.	2021-12-23	Antidiabetics	Adjuvant drug for diet therapy in type 2 diabetes patients	Dapagliflozin Propanediol hydrate → Dapagliflozin BisL-prolin
84	Manufac-tured	DM-Cure XR Tablet 10/1000mg					
85	Manufac-tured	DAFORMET XR Tab. 10/500mg	Ildong Pharmaceutical Co., Ltd.	2021-12-23	Antidiabetics	Adjuvant drug for diet therapy in type 2 diabetes patients	Dapagliflozin Propanediol hydrate → Dapagliflozin BisL-prolin
86	Manufac-tured	DAFORMET XR Tab. 10/1000mg					
87	Manufac-tured	Samsita Plus Tab. 50/500mg	Samsung Pharm Co., Ltd.	2021-12-30	Antidiabetics	Adjuvant drug for diet therapy in type 2 diabetes patients	Sitagliptin phosphate hydrate → Sitagliptin Hydrochloride hydrate
88	Manufac-tured	Samsita Plus Tab. 50/850mg					
89	Manufac-tured	Samsita Plus Tab.50/1000mg					

No.	Manufac-tured/ Imported	Product name	Company	Approval date	Detailed classification	Efficacy/Effectiveness (partially summarized)	Remarks
90	Manufac-tured	Janulitin combi tab 50/500mg	Daewon Pharm. Co., Ltd	2021-12-30	Antidiabetics	Adjuvant drug for diet therapy in type 2 diabetes patients	Sitagliptin phosphate hydrate → Sitagliptin Hydrochloride hydrate
91	Manufac-tured	Janulitin combi tab 50/850mg					
92	Manufac-tured	Janulitin combi tab 50/1000mg					

* Detailed approval information (efficacy/effectiveness, administration/dosage and precautions for use) is available at http://nedrug.mfds.go.kr.

2) Drugs with new efficacy group (4 items)

There were 4 drugs with new efficacy, all of which were manufactured: one drug for sterilization and disinfection of medical devices; one for improving jowl fat; and two for gastric mucosal lesions in acute and chronic gastritis patients. (see Table 34).

Table 34. Approval Status of Drugs in New Therapeutic Class that require Data Submission in 2021

No.	Manufac-tured/ Imported	Product name	Company	Approval date	Detailed Classification	Efficacy/Effectiveness
1	Manufac-tured	Stericlean(Hydrogen peroxide solution 35%)	Huons Medicare Co., Ltd.	2021-07-07	Miscellaneous drug for public sanitation	Sterilization and disinfection of medical instruments
2	Manufac-tured	V-OLET injection(Deoxycholic acid)	Daewoong Pharmaceutical Co., Ltd.	2021-08-06	Miscellaneous metabolic drugs	Improvement of moderately severe protruding or excessive submandibular fat in adults
3	Manufac-tured	Esotech tab. 10mg(Esomeprazole magnesium trihydrate)	Danagen.co.,Ltd.	2021-11-29	Peptic ulcer agents	Improvement of gastric mucosal lesions in acute gastritis and chronic gastritis
4	Manufac-tured	Eswonamp tab. 10mg(Esomeprazole magnesium trihydrate)	Daewon Pharm. Co., Ltd.	2021-11-29	Peptic ulcer agents	Improvement of gastric mucosal lesions in acute gastritis and chronic gastritis

3) Drugs with new composition of active substance or change only in strength (160 items)

137 new composition drugs were approved (134 manufactured, 3 imported), and of those, circulatory system drugs accounted for the majority with 118 items (86.1%). 69 hyperlipidemia combination drugs were approved (50.4%), and of those, 68 items contained Ezetimibe (98.6%). 49 hypertension/ hyperlipidemia combination drugs were approved (35.8%). The majority of newly approved composition drugs in 2021 contained Ezetimibe (hypertension/hyperlipidemia or hyperlipidemia) (80 items, 58.4%). (see Table 35).

23 items were approved with change in their strengths (16 manufactured, 7 imported). There were various types of items that were approved, including 3 metabolic drugs, 3 chemotherapy agents, 2 hypertension treatments, 2 hyperlipidemia treatments, 2 antitussive expectorants, 2 X-ray contrast agents, 1 general anesthetic, 1 ophthalmic preparation and 1 thyroid treatment (see Table 36).

Table 35. Approval Status of Drugs with New Composition that require Data Submission in 2021

No.	Manufac-tured/ Imported	Product name	Company	Approval date	Detailed classification	Active ingredient
1	Manufac-tured	EZETOVA Tab 10/20mg	Korea United Pharm Inc.	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
2	Manufac-tured	ATORVZET TAB. 10/ 40mg	Kyung Dong Pharm. Co., Ltd.	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
3	Manufac-tured	Zepitor Tab.10/ 10mg	HK inno.N	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
4	Manufac-tured	Atoezet Tab. 10/ 10mg	Korea Prime Pharm. Co., Ltd.	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
5	Manufac-tured	LIVAZET Tablet10/ 40mg	PharmGen Science Inc.	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
6	Manufac-tured	Yutozet Tab 10/10mg	Yuyu Pharma, Inc.	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
7	Manufac-tured	Azetibe Tablet 10/20mg	Alvogen Korea Co., Ltd.	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
8	Manufac-tured	Celltozet Tab. 10/ 10mg	Celltrion Pharm, Inc.	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
9	Manufac-tured	Atolow plus tab. 10/ 10mg	Sam Chun Dang Pharm. Co.,Ltd	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
10	Manufac-tured	Atoeze tab 10/20mg	KyongBo Pharmaceuticals Co., Ltd.	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
11	Manufac-tured	Celltozet Tab. 10/ 40mg	Celltrion Pharm, Inc.	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
12	Manufac-tured	LIVAZET Tablet10/20mg	PharmGen Science Inc.	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
13	Manufac-tured	Atotibe Tab. 10/ 40mg	Hutecs Korea Pharmaceutical Co., Ltd.	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
14	Manufac-tured	ATORVZET TAB. 10/20mg	Kyung Dong Pharm. Co., Ltd.	2021-01-08	Antiarteriosclerotic agents	Ezetimibe atorvastatin calciumtrihydrate
15	Manufac-tured	Atolow plus tab. 10/20mg	Sam Chun Dang Pharm. Co.,Ltd	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium Ezetimibe
16	Manufac-tured	Neustazet-A Tab. 10/20mg	Samjin Pharmaceutical Co., Ltd.	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe

No.	Manufac-tured/ Imported	Product name	Company	Approval date	Detailed classification	Active ingredient
17	Manufac-tured	Y ZET Tab. 10/20mg	YOOYOUNG Pharm. Co., Ltd.	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
18	Manufac-tured	Neustazet-A Tab. 10/ 10mg	Samjin Pharmaceutical Co., Ltd.	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
19	Manufac-tured	Vastazet Tab10/ 10mg	Reyon Pharmaceutical Co., Ltd.	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
20	Manufac-tured	Yutozet Tab10/40mg	Yuyu Pharma, Inc.	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
21	Manufac-tured	L50 Tablet10/ 10mg	Boryung Co., Ltd.	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
22	Manufac-tured	Lipozet tab. 10/ 10mg	Ahngook Pharm.	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
23	Manufac-tured	Y ZET Tab.10/ 40mg	YOOYOUNG Pharm. Co., Ltd.	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
24	Manufac-tured	Atoeve Tab.10/20mg	Hwail pharm Co., Ltd.	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
25	Manufac-tured	Apezet tab 10/ 10mg	Kukje Pharma Co., Ltd.	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
26	Manufac-tured	Azetibe Tablet 10/ 40mg	Alvogen Korea Co., Ltd.	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
27	Manufac-tured	ARVAZET Tablet 10/20mg	Korea Arlico Pharm Co., Ltd.	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
28	Manufac-tured	Lipozet tab. 10/20mg	Ahngook Pharm.	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
29	Manufac-tured	L50 Tablet10/ 40mg	Boryung Co., Ltd.	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
30	Manufac-tured	Atovanduo Tablet 10/ 10mg	DongKook Pharmaceutical Co., Ltd.	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
31	Manufac-tured	Atoeze tab 10/ 40mg	KyongBo Pharmaceuticals Co., Ltd.	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
32	Manufac-tured	Atovanduo Tablet 10/ 40mg	DongKook Pharmaceutical Co., Ltd.	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
33	Manufac-tured	Zepitor Tab.10/ 40mg	HK inno.N	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
34	Manufac-tured	Aritorine Tab. 10/ 10mg	Hana pharm	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
35	Manufac-tured	Toszet Tab. 10/ 10mg	SK Chemicals	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
36	Manufac-tured	Atoezet Tab.10/ 40mg	Korea Prime Pharm. Co., Ltd.	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
37	Manufac-tured	Lipozet tab. 10/ 40mg	Ahngook Pharm.	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
38	Manufac-tured	Celltozet Tab. 10/20mg	Celltrion Pharm, Inc.	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
39	Manufac-tured	Atoeve Tab.10/ 10mg	Hwail pharm Co., Ltd.	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
40	Manufac-tured	Azetibe Tablet 10/ 10mg	Alvogen Korea Co., Ltd.	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe

No.	Manufac-tured/ Imported	Product name	Company	Approval date	Detailed classification	Active ingredient
41	Manufac-tured	EZETOVA Tab 10/ 40mg	Korea United Pharm. Inc.	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
42	Manufac-tured	Vastazet Tab10/ 40mg	Reyon Pharmaceutical Co., Ltd.	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
43	Manufac-tured	Atotibe Tab. 10/ 10mg	Hutecs Korea Pharmaceutical Co., Ltd.	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
44	Manufac-tured	Neustazet-A Tab. 10/ 40mg	Samjin Pharmaceutical Co., Ltd.	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
45	Manufac-tured	ARVAZET Tablet 10/ 40mg	Korea Arlico Pharm Co., Ltd.	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
46	Manufac-tured	Atoeze tab 10/ 10mg	KyongBo Pharmaceuticals Co., Ltd.	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
47	Manufac-tured	Toszet Tab. 10/ 40mg	SK Chemicals	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
48	Manufac-tured	Atotibe Tab. 10/20mg	Hutecs Korea Pharmaceutical Co., Ltd.	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
49	Manufac-tured	L50 Tablet10/20mg	Boryung Co., Ltd.	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
50	Manufac-tured	Atoeve Tab.10/ 40mg	Hwail pharm Co., Ltd.	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
51	Manufac-tured	Atovanduo Tablet 10/20mg	DongKook Pharmaceutical Co., Ltd.	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium hydrateEzetimibe
52	Manufac-tured	Apezet tab 10/ 40mg	Kukje Pharma Co., Ltd.	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
53	Manufac-tured	Apezet tab 10/20mg	Kukje Pharma Co., Ltd.	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
54	Manufac-tured	EZETOVA Tab 10/ 10mg	Korea United Pharm. Inc.	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
55	Manufac-tured	Aritorine Tab. 10/20mg	Hana pharm	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
56	Manufac-tured	Atolow plus tab. 10/ 40mg	Sam Chun Dang Pharm. Co.,Ltd	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
57	Manufac-tured	ATORVZET TAB. 10/ 10mg	Kyung Dong Pharm. Co., Ltd.	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
58	Manufac-tured	Yutozet Tab10/20mg	Yuyu Pharma, Inc.	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
59	Manufac-tured	Y ZET Tab.10/ 10mg	YOOYOUNG Pharm. Co., Ltd.	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
60	Manufac-tured	Zepitor Tab.10/20mg	HK inno.N.	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
61	Manufac-tured	Aritorine Tab. 10/ 40mg	Hana pharm	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
62	Manufac-tured	Vastazet Tab10/20mg	Reyon Pharmaceutical Co., Ltd.	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
63	Manufac-tured	Toszet Tab. 10/20mg	SK Chemicals	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe

No.	Manufac-tured/ Imported	Product name	Company	Approval date	Detailed classification	Active ingredient
64	Manufac-tured	LIVAZET Tablet10/ 10mg	PharmGen Science Inc.	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
65	Manufac-tured	ARVAZET Tablet 10/ 10mg	Korea Arlico Pharm Co., Ltd.	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
66	Manufac-tured	Atoezet Tab.10/20mg	Korea Prime Pharm. Co., Ltd.	2021-01-08	Antiarteriosclerotic agents	Atorvastatin calcium ezetimibe
67	Manufac-tured	Atromega combigel soft capsule	Korea Biochem Pharm. Inc.	2021-01-28	Antiarteriosclerotic agents	Atorvastatin calcium Omega-3-acid ethyl esters 90
68	Manufac-tured	Esoca Tab. 20/600mg	GC Pharma	2021-02-05	Peptic ulcer agents	Esomeprazole magnesium trihydrate Precipitated calcium carbonate
69	Manufac-tured	Esopid Tablet20/600mg	Yuhan Corporation	2021-02-05	Peptic ulcer agents	Esomeprazole magnesium trihydrate Precipitated calcium carbonate
70	Manufac-tured	Esopid Tablet40/600mg	Yuhan Corporation	2021-02-05	Peptic ulcer agents	Esomeprazole magnesium trihydrate Precipitated calcium carbonate
71	Manufac-tured	Esocarbo tab. 40/600mg	Kyung Dong Pharm. Co., Ltd.	2021-02-05	Peptic ulcer agents	Esomeprazole magnesium trihydrate Precipitated calcium carbonate
72	Manufac-tured	Esoca Tab. 40/600mg	GC Pharma	2021-02-05	Peptic ulcer agents	Esomeprazole magnesium trihydrate Precipitated calcium carbonate
73	Manufac-tured	Esocarbo tab. 20/600mg	Kyung Dong Pharm. Co., Ltd.	2021-02-05	Peptic ulcer agents	Esomeprazole magnesium trihydrate Precipitated calcium carbonate
74	Manufac-tured	Nutri max 12 inj	Dai Han Pharm. Co., Ltd.	2021-03-25	Protein amino acid preparation	L-Methionine L-Serine L-Aspartic acid L-Glutamic acid Glycine L-Lysine hydrochloride L-proline L-Cystine L-Isoleucine L-Tryptophan L-Valine L-Tyrosine L-Alanine L-Leucine L-Threonine L-Arginine-Monohydrochloride L-Histidine-Monohydrochloride L-Phenylalanine
75	Imported	Duodart Capsule	GlaxoSmithKline	2021-05-18	Miscellaneous urogenital and anal organ drugs	Tamsulosin hydrochloride Dutasteride
76	Manufac-tured	Exator tab. 5/80/20mg	Hutecs Korea Pharmaceutical Co., Ltd.	2021-07-12	Miscellaneous circulatory system drugs	Atorvastatin calcium hydrate Valsartan Amlodipine besylate

No.	Manufac-tured/ Imported	Product name	Company	Approval date	Detailed classification	Active ingredient
77	Manufac-tured	Hypoge A tab 5/80/10mg	GENUONE Sciences Inc.	2021-07-12	Miscellaneous circulatory system drugs	Atorvastatin calcium hydrate Valsartan Amlodipine besylate
78	Manufac-tured	Hypoge A tab 5/160/ 10mg	GENUONE Sciences Inc.	2021-07-12	Miscellaneous circulatory system drugs	Atorvastatin calcium hydrate Valsartan Amlodipine besylate
79	Manufac-tured	ANAFURGE-A TAB 5/160/10mg	Aju Pharm Co., Ltd.	2021-07-12	Miscellaneous circulatory system drugs	Atorvastatin calcium hydrate Valsartan Amlodipine besylate
80	Manufac-tured	Exator tab.5/160/20mg	Hutecs Korea Pharmaceutical Co., Ltd.	2021-07-12	Miscellaneous circulatory system drugs	Atorvastatin calcium hydrate Valsartan Amlodipine besylate
81	Manufac-tured	Hypoge A tab5/80/20mg	GENUONE Sciences Inc.	2021-07-12	Miscellaneous circulatory system drugs	Atorvastatin calcium hydrate Valsartan Amlodipine besylate
82	Manufac-tured	Exator tab.5/80/10mg	Hutecs Korea Pharmaceutical Co., Ltd.	2021-07-12	Miscellaneous circulatory system drugs	Atorvastatin calcium hydrate Valsartan Amlodipine besylate
83	Manufac-tured	ANAFURGE-A TAB 5/160/20mg	Aju Pharm Co., Ltd.	2021-07-12	Miscellaneous circulatory system drugs	Atorvastatin calcium hydrate Valsartan Amlodipine besylate
84	Manufac-tured	Exator tab.5/160/10mg	Hutecs Korea Pharmaceutical Co., Ltd.	2021-07-12	Miscellaneous circulatory system drugs	Atorvastatin calcium hydrate Valsartan Amlodipine besylate
85	Manufac-tured	ANAFURGE-A TAB 5/80/10mg	Aju Pharm Co., Ltd.	2021-07-12	Miscellaneous circulatory system drugs	Atorvastatin calcium hydrate Valsartan Amlodipine besylate
86	Manufac-tured	ANAFURGE-A TAB 5/80/20mg	Aju Pharm Co., Ltd.	2021-07-12	Miscellaneous circulatory system drugs	Atorvastatin calcium hydrate Valsartan Amlodipine besylate
87	Manufac-tured	Hypoge A tab5/160/20mg	GENUONE Sciences Inc.	2021-07-12	Miscellaneous circulatory system drugs	Atorvastatin calcium hydrate Valsartan Amlodipine besylate
88	Manufac-tured	Amlovan plus tab. 5/80/5mg	Sam Chun Dang Pharm. Co.,Ltd	2021-08-27	Miscellaneous circulatory system drugs	Valsartan Rosuvastatin calcium Amlodipine besylate
89	Manufac-tured	Excresba Tab. 5/160/5mg	Hutecs Korea Pharmaceutical Co., Ltd.	2021-08-27	Miscellaneous circulatory system drugs	Valsartan Rosuvastatin calcium Amlodipine besylate
90	Manufac-tured	Excresba Tab. 5/80/10mg	Hutecs Korea Pharmaceutical Co., Ltd.	2021-08-27	Nervous system and sensory organ drugs	Valsartan Rosuvastatin calcium Amlodipine besylate
91	Manufac-tured	Amlovan plus tab. 5/160/ 5mg	Sam Chun Dang Pharm. Co.,Ltd	2021-08-27	Miscellaneous circulatory system drugs	Valsartan Rosuvastatin calcium Amlodipine besylate
92	Manufac-tured	Amlovan plus tab. 5/80/ 10mg	Sam Chun Dang Pharm. Co.,Ltd	2021-08-27	Miscellaneous circulatory system drugs	Valsartan Rosuvastatin calcium Amlodipine besylate

No.	Manufac-tured/ Imported	Product name	Company	Approval date	Detailed classification	Active ingredient
93	Manufac-tured	V-Forge R tablet5/160/ 5mg	Daewoong Bio Inc.	2021-08-27	Miscellaneous circulatory system drugs	Valsartan Rosuvastatin calcium Amlodipine besylate
94	Manufac-tured	Amlovan plus tab. 5/160/ 10mg	Sam Chun Dang Pharm. Co.,Ltd	2021-08-27	Miscellaneous circulatory system drugs	Valsartan Rosuvastatin calcium Amlodipine besylate
95	Manufac-tured	V-Forge R tablet5/80/ 10mg	Daewoong Bio Inc.	2021-08-27	Miscellaneous circulatory system drugs	Valsartan Rosuvastatin calcium Amlodipine besylate
96	Manufac-tured	Excresba Tab. 5/160/ 10mg	Hutecs Korea Pharmaceutical Co., Ltd.	2021-08-27	Miscellaneous circulatory system drugs	Valsartan Rosuvastatin calcium Amlodipine besylate
97	Manufac-tured	V-Forge R tablet5/160/ 10mg	Daewoong Bio Inc.	2021-08-27	Miscellaneous circulatory system drugs	Valsartan Rosuvastatin calcium Amlodipine besylate
98	Manufac-tured	V-Forge R tablet5/80/ 5mg	Daewoong Bio Inc.	2021-08-27	Miscellaneous circulatory system drugs	Valsartan Rosuvastatin calcium Amlodipine besylate
99	Manufac-tured	Excresba Tab. 5/80/ 5mg	Hutecs Korea Pharmaceutical Co., Ltd.	2021-08-27	Miscellaneous circulatory system drugs	Valsartan Rosuvastatin calcium Amlodipine besylate
100	Imported	Maxigesic	KyongBo Pharmaceuticals Co., Ltd.	2021-08-30	Antipyretics, analgesics, and anti-inflammatory drugs	Acetaminophen Ibuprofen sodium dihydrate
101	Manufac-tured	Duowell Plus tablet 40/20/ 10mg	Yuhan Corporation	2021-09-24	Miscellaneous circulatory system drugs	Telmisartan Rosuvastatin calcium Ezetimibe
102	Manufac-tured	Duowell Plus tablet 40/5/ 10mg	Yuhan Corporation	2021-09-24	Miscellaneous circulatory system drugs	Telmisartan Rosuvastatin calcium Ezetimibe
103	Manufac-tured	Duowell Plus tablet 80/5/ 10mg	Yuhan Corporation	2021-09-24	Miscellaneous circulatory system drugs	Telmisartan Rosuvastatin calcium Ezetimibe
104	Manufac-tured	Duowell Plus tablet 40/10/ 10mg	Yuhan Corporation	2021-09-24	Miscellaneous circulatory system drugs	Telmisartan Rosuvastatin calcium Ezetimibe
105	Manufac-tured	Rosuzet Tab. 10/2.5mg	Hanmi Pharm. Co., Ltd.	2021-09-24	Antiarteriosclerotic agents	Telmisartan Rosuvastatin calcium Ezetimibe
106	Manufac-tured	Duowell Plus tablet 80/20/ 10mg	Yuhan Corporation	2021-09-24	Miscellaneous circulatory system drugs	Telmisartan Rosuvastatin calcium Ezetimibe
107	Manufac-tured	Duowell Plus tablet 80/10/ 10mg	Yuhan Corporation	2021-09-24	Miscellaneous circulatory system drugs	Telmisartan Rosuvastatin calcium Ezetimibe
108	Manufac-tured	Rozetel Tab. 80/5/10mg	GC Pharma	2021-09-29	Miscellaneous circulatory system drugs	Telmisartan Rosuvastatin calcium Ezetimibe
109	Manufac-tured	Rozetel Tab. 40/10/ 10mg	GC Pharma	2021-09-29	Miscellaneous circulatory system drugs	Telmisartan Rosuvastatin calcium Ezetimibe
110	Manufac-tured	Rozetel Tab. 40/20/ 10mg	GC Pharma	2021-09-29	Miscellaneous circulatory system drugs	Telmisartan Rosuvastatin calcium Ezetimibe

No.	Manufac-tured/ Imported	Product name	Company	Approval date	Detailed classification	Active ingredient
111	Manufac-tured	Rozetel Tab. 80/20/ 10mg	GC Pharma	2021-09-29	Miscellaneous circulatory system drugs	Telmisartan Rosuvastatin calcium Ezetimibe
112	Manufac-tured	Rozetel Tab. 80/10/ 10mg	GC Pharma	2021-09-29	Miscellaneous circulatory system drugs	Telmisartan Rosuvastatin calcium Ezetimibe
113	Manufac-tured	Rozetel Tab. 40/5/10mg	GC Pharma	2021-09-29	Miscellaneous circulatory system drugs	Telmisartan Rosuvastatin calcium Ezetimibe
114	Manufac-tured	Ezefeno Tab.	Hyundai Pharm	2021-10-14	Antiarteriosclerotic agents	Telmisartan Rosuvastatin calcium Ezetimibe
115	Manufac-tured	Esomezole plus Tab. 40/350mg	Hanmi Pharm. Co., Ltd.	2021-10-22	Peptic ulcer agents	Telmisartan Rosuvastatin calcium Ezetimibe
116	Manufac-tured	Rosucande tablets 10/16mg	Kuhnil Biopharm. Co., Ltd.	2021-10-25	Miscellaneous circulatory system drugs	Telmisartan Rosuvastatin calcium Ezetimibe
117	Manufac-tured	CANDECANDUO tablet 20/32mg	Daewoong Bio Inc.	2021-10-25	Miscellaneous circulatory system drugs	Telmisartan Rosuvastatin calcium Ezetimibe
118	Manufac-tured	CANDECANDUO tablet 10/8mg	Daewoong Bio Inc.	2021-10-25	Miscellaneous circulatory system drugs	Telmisartan Rosuvastatin calcium Ezetimibe
119	Manufac-tured	CANDECANDUO tablet 5/16mg	Daewoong Bio Inc.	2021-10-25	Miscellaneous circulatory system drugs	Telmisartan Rosuvastatin calcium Ezetimibe
120	Manufac-tured	CANDECANDUO tablet 5/8mg	Daewoong Bio Inc.	2021-10-25	Miscellaneous circulatory system drugs	Telmisartan Rosuvastatin calcium Ezetimibe
121	Manufac-tured	Rosucande tablets 10/8mg	Kuhnil Biopharm. Co., Ltd.	2021-10-25	Miscellaneous circulatory system drugs	Telmisartan Rosuvastatin calcium Ezetimibe
122	Manufac-tured	CANDECANDUO tablet 10/16mg	Daewoong Bio Inc.	2021-10-25	Miscellaneous circulatory system drugs	Telmisartan Rosuvastatin calcium Ezetimibe
123	Manufac-tured	Rosucande tablets 5/8mg	HP&C Ltd.nil Biopharm. Co., Ltd.	2021-10-25	Miscellaneous circulatory system drugs	Telmisartan Rosuvastatin calcium Ezetimibe
124	Manufac-tured	Rosucande tablets 20/32mg	Kuhnil Biopharm. Co., Ltd.	2021-10-25	Miscellaneous circulatory system drugs	Telmisartan Rosuvastatin calcium Ezetimibe
125	Manufac-tured	Rosucande tablets 5/16mg	Kuhnil Biopharm. Co., Ltd.	2021-10-25	Miscellaneous circulatory system drugs	Telmisartan Rosuvastatin calcium Ezetimibe
126	Imported	BREZTRI AEROSPHERE 160/7.2/5.0microgram	AstraZeneca Korea	2021-11-09	Miscellaneous circulatory system drugs	Telmisartan Rosuvastatin calcium Ezetimibe
127	Manufac-tured	Amortan-R Tab. 5/160/ 5mg	CMG Pharmaceutical Co., Ltd.	2021-12-21	Miscellaneous circulatory system drugs	Telmisartan Rosuvastatin calcium Ezetimibe

No.	Manufac-tured/ Imported	Product name	Company	Approval date	Detailed classification	Active ingredient
128	Manufac-tured	Amortan-R Tab. 5/160/ 10mg	CMG Pharmaceutical Co., Ltd.	2021-12-21	Miscellaneous circulatory system drugs	Telmisartan Rosuvastatin calcium Ezetimibe
129	Manufac-tured	Amortan-R Tab. 5/80/ 10mg	CMG Pharmaceutical Co., Ltd.	2021-12-21	Miscellaneous circulatory system drugs	Telmisartan Rosuvastatin calcium Ezetimibe
130	Manufac-tured	Amortan-R Tab. 5/80/ 5mg	CMG Pharmaceutical Co., Ltd.	2021-12-21	Miscellaneous circulatory system drugs	Telmisartan Rosuvastatin calcium Ezetimibe
131	Manufac-tured	Sitaflozin tab 10/ 100mg	DongKoo Bio&Pharma Co., Ltd.	2021-12-23	Miscellaneous circulatory system drugs	Telmisartan Rosuvastatin calcium Ezetimibe
132	Manufac-tured	Rabeol Duo Tab.10/500mg (Rabeprazole sodium, Sodium bicarbonate)	Samjin Pharmaceutical Co., Ltd.	2021-12-31	Peptic ulcer agents	Telmisartan Rosuvastatin calcium Ezetimibe
133	Manufac-tured	Rabemore 10/500mg Tab. (Rabeprazole sodium, Sodium bicarbonate)	Whan In Pharm. Co., Ltd.	2021-12-31	Peptic ulcer agents	Telmisartan Rosuvastatin calcium Ezetimibe
134	Manufac-tured	RABEDUET Tab. 10/500mg (Rabeprazole sodium, Sodium bicarbonate)	DongWha Pharm. Co., Ltd.	2021-12-31	Peptic ulcer agents	Telmisartan Rosuvastatin calcium Ezetimibe
135	Manufac-tured	Rabenew Tabs. 10/500mg (Rabeprazole sodium, Sodium bicarbonate)	Yungjin Pharm.	2021-12-31	Peptic ulcer agents	Telmisartan Rosuvastatin calcium Ezetimibe
136	Manufac-tured	Rabiduo 10/500mg (Rabeprazole sodium, Sodium bicarbonate)	Dong-A ST	2021-12-31	Peptic ulcer agents	Telmisartan Rosuvastatin calcium Ezetimibe
137	Manufac-tured	Rabietduo Tablets 10/500mg (Rabeprazole sodium, Sodium bicarbonate)	Ildong Pharmaceutical Co., Ltd.	2021-12-31	Peptic ulcer agents	Telmisartan Rosuvastatin calcium Ezetimibe

* Detailed approval information (efficacy/effectiveness, administration/dosage, and precautions for use) is available at http://nedrug.mfds.go.kr

Table 36. Approval Status of Drugs with Changes in Strength that require Data Submission in 2021

No.	Manufac-tured/ Imported	Product name	Company	Approval date	Detailed classification	Efficacy/Effectiveness(partially summarized)
1	Imported	lumify ophthalmic solution, 0.025% (Brimonidine tartrate)	Bausch Health Korea Co., Ltd.	2021-01-15	Ophthalmic preparations	Relieves eye redness caused by mild irritation
2	Manufac-tured	Methimazole Bukwang Tablet 2.5mg	Bukwang Pharm Co.,Ltd	2021-01-20	Thyroid, parathyroid hormone	1. Hyperthyroidism 2. Hyperthyroidism with subthyroidectomy and radioiodine therapy
3	Imported	Rely on Perasafe (Sodium percarbonate)	Nanopharm Corp.	2021-03-10	Miscellaneous drugs for public hygiene	Disinfection and sterilization of medical instruments (including heat-sensitive endoscopes)
4	Manufac-tured	Lodien tab. 1.2 5mg (S-amlodipine nicotinate)	Hanlim Pharm. Co., Ltd.	2021-03-31	Antihypertensives	1. Hypertensive Myocardial ischemia due to fixed occlusive stable angina pectoris or coronary vasospasm dysplastic angina pectoris 2. Reducing the risk of hospitalization for angina in patients without cardiac failure or patients with cardiac output less than 40 who have been confirmed coronary heart disease by recent angiography Reducing the risk of coronary revascularization
5	Manufac-tured	Cosca tablet 25mg (Losartan Potassium)	SK Chemicals	2021-04-13	Antihypertensives	1. Hypertension 2. Nephropathy in type 2 diabetes patients with hypertension as a treatment for hypertension
6	Imported	Foster NEXThaler 200/6	KOLON Pharma	2021-04-29	Antitussive expectorants	Treatment of asthma for which the combination therapy of long-acting bronchodilators and inhaled corticosteroids is judged appropriate.
7	Imported	Foster 200/6HFA				
8	Imported	Tristel Duo Foam	HP&C Ltd.	2021-05-11	Miscellaneous drugs for public hygiene	Disinfection of ultrasonic probes and non-invasive medical devices
9	Manufac-tured	Peraonce Premix IV Drip Infusion (Peramivir hydrate)	Chong Kun Dang Pharm.	2021-05-31	Other chemo therapy treatments	Treatment of influenza A or B virus infection in adults and children2 years of age or older
10	Manufac-tured	Peramiflu Premix inj. (Peramivir hydrate)	GC Pharma	2021-05-31	Miscellaneous chemo therapy agent	Treatment of influenza A or B virus infection in adults and children 2 years of age or older
11	Manufac-tured	Raboni-D Tablet	Yuhan Corporation	2021-06-16	Miscellaneous metabolic drugs	Treatment and prevention of osteoporosis in postmenopausal women
12	Manufac-tured	EVIMAX D tablet	Daewoong Pharmaceutical Co., Ltd.	2021-06-29	Miscellaneous metabolic drugs	Treatment and prevention of osteoporosis in postmenopausal women
13	Manufac-tured	Raloduo Tablet	Jeil Pharmaceutical Co., Ltd.	2021-06-29	Miscellaneous metabolic drugs	Treatment and prevention of osteoporosis in postmenopausal women

No.	Manufac-tured/ Imported	Product name	Company	Approval date	Detailed classification	Efficacy/Effectiveness(partially summarized)
14	Manufac-tured	Glupa XR tab. 850mg (Metformin Hydrochloride)	Dalim Biotech Co., Ltd.	2021-06-30	Antidiabetics	Used alone or in combination with other oral hypoglycemic agents or insulin for treating adult patients with type 2 diabetes whose glycemic control is insufficient with diet and exercise therapy, especially in overweight diabetic patients
15	Manufac-tured	FLUENPERA Injection (Peramivir hydrate)	JW Life Science	2021-07-28	Miscellaneous chemo therapy agent	Treatment of influenza A or B virus infection in adults and children 2 years of age or older Administer within 48 hours of onset of initial symptoms of influenza infection
16	Manufac-tured	Platless Tablet 300mg (Clopidogrel Bisulfate)	Samjin Pharmaceuti cal Co., Ltd.	2021-07-28	Antiarteriosclerotic agents	Improvement of atherosclerotic symptoms in adult patients with ischemic stroke, myocardial infarction or peripheral arterial disease (hereafter omitted)
17	Manufac-tured	Suvast Tab. 2.5mg (Rosuvastatin calcium)	Hanmi Pharm. Co., Ltd.	2021-08-17	Antiarteriosclerotic agents	Primary hypercholesterolemia type IIa complex hyperlipidemia including heterozygous familial hypercholesterolemia type IIb Dietary supplement in case uncontrollable through diet and exercise
18	Manufac-tured	Byfavo Inj. 20mg (Remimazolam Besylate)	Hana pharm	2021-08-30	General anesthetics	1. Induction and maintenance of general anesthesia in adults 2. Induction and maintenance of sedation during short-time treatment within 30 minutes in adults
19	Imported	CHOYANG PAA15 (Peracetic acid solution)	Choyang Medical Industry	2021-09-27	Drugs for public hygiene	Sterilization and disinfection of medical instruments
20	Manufac-tured	IOBRIX INJ.270 (Iohexol)	Taejoon Pharmaceuti cal Co., Ltd.	2021-11-08	X-ray contrast agent	1. Myelogram 2. Angiography 3. CT Contrast Enhancement 4. Body cavity contrast, arthroscopic imaging, uterine tubal contrast imaging, salivary gland imaging, digestive tract imaging
21	Manufac-tured	IOBRIX INJ.320 (Iohexol)				
22	Imported	Ebixa 20mg tablets (Memantine Hydrochloride)	Lundbek Korea Co., Ltd.	2021-11-10	Miscellaneous central nervous system drugs	Treatment of moderate to severe Alzheimer's disease
23	Manufac-tured	ABILIFY Tablets 1mg (Aripiprazole)	Korea Otsuka Pharmaceuti cal	2021-12-03	Psychoneural agent	1. Schizophrenia 2. Treatment of acute manic and mixed episodes associated with bipolar disorder 3. Adjunctive therapy for major depressive disorder 4. Hypersensitivity associated with autism disorder 5. Tourette's disorder

4) Drugs with new administration/dosage (2 items)

There were two chemical drugs that were approved with new administration and dosage, and both were manufactured items. These include an antipyretic and analgesic that are developed for injection

into children, and a hemostatic agent with added regimens that limit the reuse of thrombin, approved by conbining tissue restoration biomaterials and thrombin lyophilized powder. (see Table 37).

Table 37. Approval Status of Drugs with New Mode of Administration/Dosage that require Data Submission in 2021

No.	Manufac-tured/ Imported	Product name	Company	Approval date	Detailed classification	Efficacy/Effectiveness (partially omitted)
1	Manufac-tured	Newaminophen premix Inj. (Acetaminophen)	Woosung Pharma. Inc.	2021-03-15	Antipyretics, analgesics, and anti-inflammatory drugs	Administered intravenously, limited to adults and children weighing 10kg or more (2 years or older) Adults weighing 50 kg or more (Hereafter omitted)
2	Manufac-tured	Endostopi Hemostatic (Thrombin)	BMI Korea	2021-12-15	Syptic	Biomaterials for tissue repair (sodium hyaluronate) are used to form and maintain mucosal elevations in gastric tumors during endoscopic mucosal resection. Thrombin may be used for bleeding sites that occur after the surgery. (See each administration/dose) This product is applicable only when the tissue restoration biomaterial (sodium hyaluronate) and thrombin are used together. It should be discared together after the packaging is damaged and the thrombin must not be used in the future. (Hereafter omitted)

* Detailed approval information (efficacy/effectiveness, administration/dosage, and precautions for use) is available at http://nedrug.mfds.go.kr.

5) Drugs with new dosage form (same route of administration) (22 items)

22 chemical drugs were approved with new dosage forms (same route of administration) (18 manufactured, 4 imported).

The development types include: 10 film-coated tablets developed as orally disintegrating tablets (45.4%); 5 tablets that were developed as sustained-release tablets (tablets or capsules) from existing immediate-release tablets (22.7%); and 3 ampules or vials that were

developed as prefilled syringes (13.6%). Additionally, existing tablets that were developed into suspension granules, film coating to oral disintegrating films, and fine grains to tablets were approved (see Table 38).

Table 38. Approval Status of Drugs with New Dosage Form (same route of administration) that require Data Submission in 2021

No.	Manufac-tured/ Imported	Product name	Company	Approval date	Detailed classification	Efficacy/Effectiveness (partially summarized)	New dosage form
1	Manufac-tured	Ramset prefilled Inj. (Ramosetron Hydrochloride)	Hana pharm	2021-01-19	Emetic, antiemetic	1. Prevention of nausea and vomiting caused by administration of anticancer drugs such as cisplatin 2. Prevention of nausea and vomiting after surgery	Ampule → Prefilled syringe
2	Manufac-tured	Mucosta SR tablets 150mg(Rebamipide)	Korea Otsuka Pharmaceutical	2021-01-20	Peptic Ulcer agents	Gastric mucosal lesions of the following diseases Improvement of erosive bleeding redness edema Acute exacerbation of acute gastritis and chronic gastritis	IR tablet → ER tablet
3	Manufac-tured	Yoosmezole DDR Cap. 20mg(Esomeprazole magnesium dihydrate)	YOOYOUNG Pharm. Co., Ltd.	2021-02-24	Peptic Ulcer agents	1. Treatment for Gastro-esophageal reflux disease GERD, erosive reflux esophagitis Long-term maintenance therapy to prevent recurrence in patients with esophagitis	IR tablet → ER capsule
4	Manufac-tured	Yoosmezole DDR Cap. 40mg(Esomeprazole magnesium dihydrate)					
5	Manufac-tured	Esotech DDR Cap. 20mg(Esomeprazole magnesium dihydrate)	Daewon Pharm. Co., Ltd.	2021-02-24	Peptic Ulcer agents	1. Treatment for Gastro-esophageal reflux disease GERD, erosive reflux esophagitis Long-term maintenance therapy to prevent recurrence in patients with esophagitis	IR tablet → ER capsule
6	Manufac-tured	Esotech DDR Cap. 40mg(Esomeprazole magnesium dihydrate)					
7	Imported	Xofluza granule for oral suspension 2mg/mL(Baloxavir Marboxil)	Roche Korea	2021-02-24	Other chemothera-peutic agents	1. Treatment for influenza infection Treatment of influenza A or B virus infection in adults and adolescents 12 years of age or older Start administration within 48 hours of the onset of the initial symptoms of influenza infection (hereinafter omitted).	Tablet → Granule for oral suspension
8	Manufac-tured	Nicobreak Orodispersible Film 0..5mg(Varenicline salicylate)	CTCBIO INC.	2021-04-13	Drugs not classified separately and not primarily intended for treatment	Adjuvant therapy for smoking cessation treatment	Film coating tablet → Orally disintegra-ting tablet
9	Manufac-tured	Nicobreak Orodispersible Film 1mg(Varenicline salicylate)					

No.	Manufac-tured/ Imported	Product name	Company	Approval date	Detailed classification	Efficacy/Effectiveness (partially summarized)	New dosage form
10	Imported	Kremezin Tablet(Spherical carbonaceouse adsorbent)	HK inno.N.	2021-08-27	Antidote	Improvement of uremia symptoms for chronic renal failure progression and delay in the introduction of dialysis	Fine granule → Tablet
11	Imported	Fresofol PFS 1% MCT(Propofol)	Fresenius Kabi Korea Ltd.	2021-10-13	General anesthetics	1. Induction and maintenance of general anesthesia in adults and children 3 years of age or older 2. Sedation of critically ill patients on artificial respiration 3. Conscious sedation during surgery and diagnosis	Ampule, vial → Prefilled
12	Imported	Fresofol PFS 2% MCT(Propofol)					Vial → Prefilled
13	Manufac-tured	Nagran ODT 2.5mg (Naratriptan Hydrochloride)	Yuyu Pharma, Inc.	2021-10-18	Antipyretics, analgesics, and antiinflam-matory drugs	Prompt relief of migraine with or without symptoms	Film coating tablet → Orally disintegrating tablet
14	Manufac-tured	SUVARO OD Tablet 5mg (Rosuvastatin calcium(anaplastic))	BCWorld Pharm. Co., Ltd.	2021-12-02	Antiarterio-sclerotic agents	1. Primary hypercholesterolemia type IIa complex hyperlipidemia including heterozygous familial hypercholesterolemia type IIb Dietary supplement in case uncontrollable through diet and exercise(hereafter omitted)	Film coating tablet → Orally disintegrating tablet
15	Manufac-tured	SUVARO OD Tablet 10mg (Rosuvastatin calcium(anaplastic))	BCWorld Pharm. Co., Ltd.				
16	Manufac-tured	SUVARO OD Tablet 20mg (Rosuvastatin calcium(anaplastic))	BCWorld Pharm. Co., Ltd.				
17	Manufac-tured	ROSUVARO OD Tablet 5mg (Rosuvastatin calcium(anaplastic))	BCWorld Healthcare	2021-12-07	Antiarterio sclerotic agents	1. Primary hypercholesterolemia type IIa complex hyperlipidemia including heterozygous familial hypercholesterolemia type IIb Dietary supplement in case uncontrollable through diet and exercise(hereafter omitted)	Film coating tablet → Orally disintegrating tablet
18	Manufac-tured	ROSUVARO OD Tablet 10mg (Rosuvastatin calcium(anaplastic))	BCWorld Healthcare				
19	Manufac-tured	ROSUVARO OD Tablet 20mg (Rosuvastatin calcium(anaplastic))	BCWorld Healthcare				
20	Manufac-tured	Edoxia Orally disintegrating Tablets 15mg (Edoxaban tosylate hydrate)	Dong-A ST	2021-12-21	Anticoagulant	1. Reducing the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation 2. Treatment of deep vein thrombosis and pulmonary embolism 3. Reducing the risk of recurrence of deep vein thrombosis and pulmonary embolism	Film coating tablet → Orally disintegrating tablet
21	Manufac-tured	Edoxia Orally disintegrating Tablets 30mg (Edoxaban tosylate hydrate)					
22	Manufac-tured	Edoxia Orally disintegrating Tablets 60mg (Edoxaban tosylate hydrate)					

* Detailed approval information (efficacy/effectiveness, .administration/dosage, and precautions for use) is available at http://nedrug.mfds.go.kr.

3

Approval Status of Biopharmaceuticals

3. Approval Status of Biopharmaceuticals

The status of biopharmaceuticals (including advanced biological products) approved in 2021 indicates that there were 12 new drugs (excluding new drugs removed from the orphan drug list, etc.); 33 drugs that require data submission (excluding orphan drugs) (25 other drugs that require data submission); and 7 orphan drugs (excluding three new orphan drugs) (see Table 39). In detail, 14 biologics, 21 recombinant protein products, and 18 advanced biological products (including re-approved products) were approved (see Table 40).

Table 39. Approval Status of Biopharmaceuticals (including Advanced Biological Products) by Review Type in 2021

<Including drugs for export and drug substances>

<table>
<tr><th>Type</th><th colspan="4">Review type</th><th>Number of approved items</th></tr>
<tr><td>1</td><td rowspan="2">New drugs (12)</td><td colspan="3">New drugs</td><td>9</td></tr>
<tr><td>2</td><td colspan="2">New orphan drugs</td><td rowspan="2">Orphan drugs (10)</td><td>3</td></tr>
<tr><td>3</td><td colspan="3">Orphan drugs</td><td>7</td></tr>
<tr><td>4</td><td colspan="4">Drugs that require data submission</td><td>33</td></tr>
<tr><td>4-1</td><td colspan="4">Incrementally modified biopharmaceuticals</td><td>2</td></tr>
<tr><td>4-2</td><td colspan="2" rowspan="2">Drugs that require data submission</td><td colspan="2">Biosimilar products</td><td>6</td></tr>
<tr><td>4-3</td><td colspan="2">Other drugs that require data submission</td><td>25</td></tr>
<tr><td colspan="5">Total</td><td>52</td></tr>
</table>

<Excluding drugs for export and drug substances>

Type	Review type			Number of approved items
1	New drugs (12)	New drugs		9
2		New orphan drugs	Orphan drugs (10)	3
3	Orphan drugs			7
4	Drugs that require data submission			31
4-1	Incrementally modified biopharmaceuticals			2
4-2	Drugs that require data submission	Biosimilar products		6
4-3		Other drugs that require data submission		23
Total				50

Table 40. Approval Status of Biopharmaceuticals (including Advanced Biological products) in 2021

<Including drugs for import and drug substances>

Type		Total	Number of approved items		Remarks
			Manufac-tured	Import-ed	
Total		52	28	24	
Biologics		15	10	5	New drugs(5), Drugs that require data submission (10 items, including drugs for export (1))
Recombinant Protein Products		19	3	16	New drugs(5), Orphan drugs (4, excluding new orphan drugs), Drugs that require data submission (10 items, including substance (1))
Advanced Biological products	Cell therapy products	15	15	0	Orphan drugs (2), Drugs that require data submission (13) * All re-approved#
	Gene therapy products	3	0	3	New drugs(2), Orphan drugs (1, excluding new orphan drugs)
Others		0	0	0	-

* Corresponds to the re-approval of previously approved cell therapy products under the Act on the Safety of and Support for Advanced Regenerative Medicine and Advanced Biological Products ADDENDA Article 2.

<Excluding drugs for export and drugs substances>

Type		Total	Number of approved items		Remarks
			Manufac-tured	Import-ed	
Total		50	26	24	
Biologics		14	9	5	New drugs(5), Drugs that require data submission (9)
Recombinant protein products		18	2	16	New drugs(5), Orphan drugs (4, excluding new orphan drugs), Drugs that require data submission (11)
Advanced pharmaceutical products	Cell therapy products	15	15	0	Orphan drugs (2), Drugs that require data submission (13) * All re-approved#
	Gene therapy products	3	0	3	New drugs(2), Orphan drugs (1, excluding new orphan drugs)
Others		0	0	0	-

3.1. Approval Status of Biologics

A total of 15 biologics were approved in 2021 (10 manufactured items, 5 imported / 8 vaccines, and 7 botulinum toxins).

In 2019, 6 items were approved (6 manufactured items / 4 vaccines, 2 botulinum toxins). In 2020, 20 items were approved, showing an increase in the number of approved products (18 manufactured items, 2 imported items / 9 vaccines, 7 botulinum toxins, 4 blood products). However, the number of approved biologics decreased slightly in 2021.

For example, in 2021, 8 vaccines were approved, including 6 corona virus infection-19 (hereinafter COVID-19) vaccines, 1 herpes zoster vaccine and 1 pneumonia vaccine (see Table 41).

Three viral vector vaccines and three mRNA vaccines were approved as COVID-19 vaccines. The viral vector vaccines use the method of inserting the COVID-19 virus surface antigen gene into the virus, which delivers them into human cells. Once delivered into human cells, the antigenic proteins are then synthesized within the body, inducing the production of neutralizing antibodies.

The mRNA vaccines use the method of synthesizing antigenic proteins in the body by injecting the COVID-19 virus surface antigen gene in the form of mRNA. This protein neutralizes and eliminates the virus when it invades the human body by inducing the production of neutralizing antibodies.

As for the virus vector vaccines, ‘Vaxzevria solution for injection (SARS-CoV-2 Virus vector vaccine)’, which is manufactured and

marketed by AstraZeneca Korea was approved as a new drug, and 'Vaxzevria solution for injection (SARS-CoV-2 Virus vector vaccine)', an imported product from the same company was approved as a drug that requires data submission. 'COVID-19 Vaccine Janssen (SARS-CoV-2 Virus vector vaccine)' from Janssen Korea Ltd. was also approved as a new drug as a viral vector vaccine.

For the mRNA vaccine, 'Comirnaty Injection (Tozinameran) (SARS CoV-2 mRNA Vaccine)' from Pfizer Korea Ltd. and 'SPIKE(SARS corona virus-2 mRNA vaccine)' imported by GC Pharma were approved as new drugs, and 'SPIKE(SARS corona virus-2 mRNA vaccine),' which is manufactured and marketed by Moderna Korea Co., Ltd. was approved as a drug that requires data submission.

As for pneumococcal vaccines, 'Skypneumo Prefilled Syringe (Pneumococcal/Diphtheria CRM197 Protein Conjugated Vaccine)' from SK Bioscience was approved. It may be used to prevent invasive diseases caused by pneumococci in infants from 6 weeks to 6 months of age or adults 50 years of age or older.

For the herpes zoster vaccine, 'Shingrix powder and suspension for suspension for injection [Herpes zoster vaccine (recombinant, adjuvanted)] [recombinant protein]' from GlaxoSmithKline was approved as a new drug. It may be used to prevent herpes zoster in adults 50 years of age or older or those 18 years of age or older that have or are expected to have a high risk of herpes zoster due to immunosuppression or immunodepression from disease or treatment.

In the case of botulinum toxins, 4 new items were approved in 2016, 2 items in 2017, 1 item in 2018, 2 items in 2019 (1 for domestic use, 1 for

export), 7 items in 2020 (7 items for export), and 2 items in 2021(6 for domestic use, 1 for export) (see Table 41).

Among the botulinum toxins approved in 2021, 'Botulax Inj. 300units' from Hugel Co., Ltd. was approved for treating muscle stiffness (upper extremity function) and equinus deformity.

Six items were approved for temporarily improving moderate to severe glabellar lines related to corrugator muscle and/or procerus muscle activity in adults between ages 19 and 65. The products are: 'Liztox Inj. 50 units' and 'Liztox Inj. 200 units' from Huons , 'WonderTox Inj. 50 units' and 'WonderTox Inj. 200 units' from Chong Kun Dang Pharm, 'Vv toxin Inj. 100 Units', from Humedix Co., Ltd., and 'Jetema The Toxin Inj. 200U (for export)' from Jetema Co., Ltd.

The MFDS has operated the "Global Vaccine Commercialization Support Group" since 2010 as part of its customized support to enhance Korea's capacity for vaccine self-sufficiency.

The Ministry plans to increase the nation's self-sufficiency in essential preventive vaccines and critical vaccines through continuous technical support.

Table 41. List of Approved Biologics in 2021

No.	Manufac-tured/ Imported	Product name	Ingredient	Company	Approval date	Efficacy/Effectiveness (partially summarized)	Re-marks
1	Manufac-tured	Vaxzevria solution for injection	Recombinant coronavirus spike protein expression adenoviral vector	AstraZeneca Korea	2021-02-10	Prevention of COVID-19 caused by SARS-CoV-2 virus in 18 years of age or older	New drug
2	Imported	Comirnaty	SARS coronavirus-2	Pfizer Korea	2021-03-05	Prevention of COVID-19	New

No.	Manufac-tured/ Imported	Product name	Ingredient	Company	Approval date	Efficacy/Effectiveness (partially summarized)	Re-marks
		Injection(Tozinameran)(SARS CoV-2 mRNA Vaccine)	spike protein expression messenger ribonucleic acid (Tozinameran)	Ltd.		caused by SARS-CoV-2 virus in children 12 years of age or older	drug
3	Imported	COVID-19 Vaccine Janssen	Recombinant coronavirus spike protein expression adenoviral vector	Janssen Korea Ltd.	2021-04-07	Prevention of COVID-19 caused by SARS-CoV-2 virus in 18 years of age or older	New drug
4	Imported	Moderna COVID-19 vaccine (SARS corona virus-2 mRNA vaccine) → (Product name changed to) SPIKE(SARS corona virus-2 mRNA vaccine)	SARS coronavirus-2 spike protein expression messenger ribonucleic acid	GC Pharma	2021-05-21	Prevention of COVID-19 caused by SARS-CoV-2 virus in 18 years of age or older	New drug
5	Imported	Shingrix powder and suspension for suspension for injection [Herpes zoster vaccine (recombinant, adjuvanted)]	Recombinant varicella zoster virus glycoprotein E	GlaxoSmithKline	2021-09-06	Prevention of herpes zoster - Adults 50 years of age or older - Persons 18 years of age or older who have or are expected to have a high risk of herpes zoster from immunodepression or immuno-suppression due to disease or treatment	New drug
6	Manufac-tured	Botulax 300U	Clostridium botulinum type A toxin	Hugel Inc.	2021-01-28	1. Muscle stiffness: Treatment of upper extremity stiffness related to stroke in adults 20 years of age or older 2. Treatment of Dynamic Equinus Foot Deformity due to stiffness in pediatric cerebral palsy patients 2 years of age or older	Drug that require data sub-mission
7	Manufac-tured	Vv Toxin Inj. 100U	Clostridium botulinum type A toxin	Humedix Co., Ltd.	2021-03-11	Temporary improvement of moderate to severe glabellar lines related to corrugator muscle and/or procerus muscle activity in adults between ages 19 and 65.	Drug that require data sub-mission
8	Imported	Vaxzevria solution for injection	Recombinant coronavirus spike protein expression adenoviral vector	AstraZeneca Korea	2021-05-21	Prevention of COVID-19 caused by SARS-CoV-2 virus in 18 years of age or older	Drug that require data sub-mission
9	Manufac-tured	Skypneumo Prefilled Syringe	Purified Pneumococcal polysaccharide	SK Bioscience	2021-06-04	1. Prevention of the following diseases in infants aged 6 weeks to 6 months	Drug that require

No.	Manufac-tured/ Imported	Product name	Ingredient	Company	Approval date	Efficacy/Effectiveness (partially summarized)	Re-marks
			(Serotype 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 23F)-Diphtheria CRM197 protein conjugate			1) Prevention of invasive diseases caused by pneumococci 2) Prevention of acute otitis media caused by pneumococci 3) Prevention of pneumonia caused by pneumococci 2. Prevention of invasive diseases caused by pneumococci in adults 50 years of age or older	data sub-mission
10	Manufac-tured	Liztox Inj. 50U (Export name: Hutox 50U)	Clostridium botulinum type A toxin	Huons	2021-06-15	Temporary improvement of moderate to severe glabellar lines related to corrugator muscle and/or procerus muscle activity in adults between ages 19 and 65.	Drug that require data sub-mission
11	Manufac-tured	WonderTox 50U	Clostridium botulinum type A toxin	Chong Kun Dang Pharm	2021-06-15	Temporary improvement of moderate to severe glabellar lines related to corrugator muscle and/or procerus muscle activity in adults between ages 19 and 65.	Drug that require data sub-mission
12	Manufac-tured	Liztox Inj. 200U (Export name: Hutox 200U)	Clostridium botulinum type A toxin	Huons	2021-07-09	Temporary improvement of moderate to severe glabellar lines related to corrugator muscle and/or procerus muscle activity in adults between ages 19 and 65.	Drug that require data sub-mission
13	Manufac-tured	WonderTox Inj. 200U	Clostridium botulinum type A toxin	Chong Kun Dang Pharm.	2021-07-09	Temporary improvement of moderate to severe glabellar lines related to corrugator muscle and/or procerus muscle activity in adults between ages 19 and 65.	Drug that require data sub-mission
14	Manufac-tured	SPIKE(SARS corona virus-2 mRNA vaccine)	SARS coronavirus-2 spike protein expression messenger ribonucleic acid	Moderna Korea Co., Ltd.	2021-12-13	Prevention of COVID-19 caused by SARS-CoV-2 virus in 18 years of age or older	Drug that require data sub-mission
15	Manufac-tured	Jetema The Toxin Inj. 200U(For export)	Clostridium botulinum type A toxin	Jetema Co., Ltd.	2021-10-29	Temporary improvement of moderate to severe glabellar lines related to corrugator muscle and/or procerus muscle activity in adults between ages 19 and 65.	For export

* Detailed approval information (efficacy/effectiveness, administration/dosage, and precautions for use) is available at http://nedrug.mfds.go.kr.

3.2. Approval Status of Recombinant Protein Products

In 2021, 19 recombinant protein products were newly approved (3 manufactured, 16 imported): these include 5 new drugs (including new orphan drugs); 4 orphan drugs (excluding 1 new orphan drug); and 10 drugs that require data submission (including one drug substance) (see Table 42).

In 2021, 4 ingredients and 5 items were designated as new drugs (including orphan drugs). This showed similar amount to that of 2020 as 3 ingredients and 5 items were approved in 2020.

As for orphan drugs (excluding new orphan drugs), 4 ingredients and 4 items were approved in 2021, showing a decrease from those that were approved in 2020 (6 ingredients and 10 items).

2 incrementally modified drugs (same ingredient) were approved in 2021, leaving 2021 to be the second year to approve incrementally modified drugs (the first was approved in 2015).

'Regkirona 960mg (Regdanvimab) (monoclonal antibody, recombinant protein)' (Celltrion Pharm, Inc., approved on Feb. 2, 2021) is a drug used to treat COVID-19, and was approved as the 32nd domestically developed new drug. The active ingredient Regdanvimab is a monoclonal antibody that binds to where the human cell would usually bind on with the COVID-19 virus. This prevents the virus from penetrating the cell by inhibiting the interaction between the COVID-19 virus and human cells.

'Rolontis Prefilled Syringe Inj. (Eflapegrastim)' (Hanmi Pharm.Co., Ltd., approved on Mar. 18, 2021) is a modified form of granulocyte colony-stimulating factor, covalently bound through a polyethylene

glycol linkage of human granulocyte colony-stimulating factor (G-CSF) analog and human immunoglobulin G4 (IgG4) Fc fraction. It was approved as the 33rd domestically developed new drug, and was approved to reduce the duration of severe neutropenia in patients that are receiving cytotoxic chemotherapy for solid cancer and malignant lymphoma.

'Ajovy solution for injection in Autoinjector (Fremanezumab, recombinant protein)' and 'Ajovy solution for injection in Pre-Filled Syringe (Fremanezumab, recombinant protein)' (Teva-Handok, approved on Jul. 27, 2021) are monoclonal antibodies that bind to calcitonin gene-related peptide (CGRP) lingand, inhibiting it from binding to the receptor. By doing so, the antibodies prevent neurogenic inflammation caused by the CGRP's influence on the blood vessels in the brain. They were approved as new drugs to prevent migraine in adults.

'Takhzyro(Lanadelumab)' (Takeda Pharmaceuticals Co., Ltd., approved on Feb. 26, 2021) was approved as a new orphan drug to prevent routine hereditary angioedema attacks in adults and adolescents (ages 12 years and older). The active ingredient Lanadelumab binds to the plasma kallikrein in hereditary angioedema and inhibits the proteolytic activity of active plasma kallikrein.

'Enspring prefilled syringe (satralizumab)' (Roche Korea, approved on Apr. 25, 2021) is an IgG2 monoclonal antibody, that pH-dependently binds to IL-6. It was approved as an orphan drug to treat neuromyelitis opitca spectrum disorder in anti-aquaporin-4 antibody-positive adults

through binding, which inhibits the IL-6's signaling pathway.

'Uplizna Inj. (inebilizumab)' (Mitsubishi Tanabe Pharma Korea Co.,Ltd., approved on Aug. 5, 2021) is an orphan drug to treat neuromyelitis opitca spectrum disorder in anti-aquaporin-4 antibody-positive adult patients. It is a monoclonal antibody that targets B cells expressing CD-19 and depletes B cells to prevent the production of anti-aquaporin antibodies.

'Besremi (Lopeg Interferon alpha-2b, recombinant protein)' (Pharma Essentia Korea, approved on Oct. 13, 2021) was approved as an orphan drug used to treat polycythemia vera patients in the low risk-group (limited to patients requiring cytoreduction therapy), and those in the high-risk group without splenomegaly.

'Mylotarg injection 4.5mg (gemtuzumab ozogamicin)' (Pfizer Korea Ltd., approved on Nov. 18, 2021) is a CD33-targeting antibody-drug conjugate (ADC) with a linkage between an N-acetyl-gamma calicheamicin, a cytotoxic agent, and the human CD33 antigen by a linker. It was approved as an orphan drug to treat adult patients with newly diagnosed CD33-positive acute myeloid leukemia (AML).

'Phesgo Subcutaneous Injection 600/600mg (Pertuzumab/Trastuzumab)' and 'Phesgo Subcutaneous Injection 1200/600mg (Pertuzumab/Trastuzumab)' (Roche Korea Co., Ltd., approved on Sep. 6, 2021) are combination drugs made up with two ingredients (Intrastuzumab (Herceptin) and Pertuzumab (Perjeta)) from previously approved items. The injections

were developed as subcutaneous injections, and were approved as incrementally modified drugs to treat metastatic and early breast cancer. They were proven to shorten administration time and to improve administration convenience.

For biosimilar drugs, 4 ingredients and 6 items were approved. Since the world's first approval of monoclonal antibody similar in 2012, 22 ingredients and 35 items were approved until 2021. Among them, 14 ingredients and 24 items were domestically developed (see Table 43).

'Onbevzi inj. (Bevacizumab)' (Samsung Bioepis, approved on Mar. 11, 2021) is a domestic biosimilar drug developed with Roche Korea's Avastin Inj. (Bevacizumab) as a reference drug.

'Zyrabev (Bevacizumab)' (Pfizer Korea Ltd., approved on May 17, 2021) is a domestic biosimilar drug developed with Roche Korea's Avastin Inj. (Bevacizumab) as a reference drug.

'SciTropin A 15mg (45IU) (Somatropin)' (SciGen Korea. co., Ltd., approved on Jul. 7, 2021) is a biosimilar drug developed in addition to 'SciTropin A 5 mg (15IU) (Somatropin)' and 'SciTropin A 10mg (30IU) (Somatropin)', both of which were approved on January 28, 2014, with Pfizer Korea Ltd.'s Genotropin (Somatropin) as a reference drug.

'Yuflyma PFS 40mg/0.4mL (Adalimumab, recombinant protein)' and 'Yuflyma 40mg/0.4mL (Adalimumab, recombinant protein)' (Celltrion Pharm, Inc., approved on Oct. 15, 2021) are domestic biosimilar drugs

developed with AbbVie Korea's Humira 40mg/0.4mL (Adalimumab) as a reference drug.

'Bonsity pen injection (Teriparatide)' (Pharmbio Korea Inc., approved on Nov. 16, 2021) is a biosimilar drug developed with Lilly Korea's Forsteo (Teriparatide) as a reference drug.

While the number of new drug items that were approved in 2021 (including orphan drugs) was the same as 2020, the number of approved orphan drugs decreased, and the overall number of approved recombinant protein products decreased as well.

Table 42. List of Approved Recombinant Protein Products in 2021

No.	Manufac-tured/ Imported	Product name	Ingredient	Company	Approval date	Efficacy/Effectiveness (partially summarized)	Re-marks
1	Manufactured	Regkirona 960mg (Regdanvimab)	Regdanvimab	Celltrion Pharm, Inc.	2021-02-05	Treatment of all patients with mild to moderate severity in the high-risk group who meet all of the following criteria as adults diagnosed with COVID-19 through PCR test, etc. 1) Those whose oxygen saturation exceeds 94% in indoor air 2) Those who do not need supplemental oxygen supply 3) Those who developed symptoms within 7 days before administration	New drug
2	Manufactured	Rolontis Prefilled Syringe Inj.	Eflapegrastim	Hanmi Pharm. Co.,Ltd.	2021-03-18	Reduced duration of severe neutropenia in patients receiving cytotoxic chemotherapy for solid cancer and malignant lymphoma	New drug
3	Imported	Ajovy solution for injection in Pre-Filled Syringe	Fremanezumab	Teva-Handok	2021-07-27	Prevention of migraine in adults	New drug
4	Imported	Ajovy solution for injection in Autoinjector					New drug
5	Imported	Takhzyro	Lanadelumab	Takeda Pharmaceu-ticals Co., Ltd.	2021-02-26	Routine prevention of hereditary angioedema attacks in adults and adolescents (ages 12 years and older)	New orphan drug
6	Imported	Enspring	Satralizumab	Roche Korea	2021-04-25	Treatment of neuromyelitis opitca	Orphan

No.	Manufac-tured/ Imported	Product name	Ingredient	Company	Approval date	Efficacy/Effectiveness (partially summarized)	Re-marks
		prefilled syringe				spectrum disorder in anti-aquaporin-4 antibody-positive adults	drug
7	Imported	Uplizna Inj.	Inebilizumab	Mitsubishi Tanabe Pharma Korea Co.,Ltd.	2021-08-05	Treatment of neuromyelitis opitca spectrum disorder in anti-aquaporin-4 antibody-positive adults	Orphan drug
8	Imported	Besremi	Lopeg Interferon alpha-2b	Pharma Essentia Korea	2021-10-13	Treatment of polycythemia vera patients in the low risk-group (limited to patients requiring cytoreduction therapy), and without splenomegaly accompanying the symptoms of the high-risk group.	Orphan drug
9	Imported	Mylotarg injection 4.5mg	Gemtuzumab ozogamicin	Pfizer Korea Ltd.	2021-11-18	Treatment of adult patients with newly diagnosed CD33-positive acute myeloid leukemia (AML)	Orphan drug
10	Imported	Phesgo Subcutaneous Injection 600/600mg	Pertuzumab/Trastuzumab	Roche Korea Co., Ltd.	2021-09-06	○ Metastatic breast cancer - Co-administration with docetaxel for HER2-positive patients with metastatic or unresectable locally recurrent breast cancer ○ Early breast cancer - Co-administration with chemotherapy as adjuvant therapy before surgery for patients with locally advanced, inflammatory or early stage HER2-positive breast cancer - Co-administration with chemotherapy as an adjuvant treatment for HER2-positive early breast cancer patients with high recurrence risk	Incre-mentally modified drug
11	Imported	Phesgo Subcutaneous Injection 1200/600mg					Incre-mentally modified drug
12	Imported	Onbevzi inj.	Bevacizumab	Samsung Bioepis	2021-03-11	· Metastatic colorectal cancer · Metastatic breast cancer · Non-small cell lung cancer · Advanced or metastatic renal cell carcinoma · Glioblastoma · Epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal carcinoma · Cervical cancer	Biosimilar drug
13	Imported	Zyrabev	Bevacizumab	Pfizer Korea Ltd.	2021-05-17	· Metastatic colorectal cancer · Metastatic breast cancer · Non-small cell lung cancer · Advanced or metastatic renal cell carcinoma · Glioblastoma · Epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal carcinoma · Cervical cancer	Biosimilar drug
14	Imported	SciTropin A 15mg(45IU)	Somatropin	SciGen Korea Co., Ltd	2021-07-09	Children Growth failure in children due to pituitary growth hormone secretion disorder, etc. Adult	Biosimilar drug

No.	Manufac-tured/ Imported	Product name	Ingredient	Company	Approval date	Efficacy/Effectiveness (partially summarized)	Re-marks
						Growth hormone replacement therapy in adults with growth hormone deficiency confirmed by two dynamic test	
15	Imported	Yuflyma PFS 40mg/0.4mL	Adalimumab	Celltrion Pharm, Inc.	2021-10-15	Adult Rheumatoid arthritis, psoriatic arthritis, etc. Children Crohn's disease in children, idiopathic arthritis in children, etc.	Biosimilar drug
16	Imported	Yuflyma 40mg/0.4mL					Biosimilar drug
17	Imported	Bonsity pen injection	Teriparatide	Pharmbio Korea Inc.	2021-11-16	Treatment of osteoporosis in postmenopausal women and men at high risk of fractures Treatment of osteoporosis associated with continuous glucocorticoid therapy in women and men at high risk of fracture	Biosimilar drug
18	Imported	Tremfya One-Press Autoinjector	Guselkumab	Janssen Korea Ltd.	2021-05-24	Plaque psoriasis, Palmoplantar pustulosis, psoriatic arthritis	Drug requiring data submi-ssion
19	Manufactured	Yuflyma undiluted solution	Adalimumab	Celltrion pharm. Inc.	2021-10-15	For dispensing or manufacturing pharmaceuticals	Drug substance

* Detailed approval information (efficacy/effectiveness, administration/dosage, and precautions for use) is available at http://nedrug.mfds.go.kr.

Table 43. List of Approved Biosimilar Products (2012~2021)

No.	Product name	Company	Reference drug (Ingredient)	Efficacy/Effectiveness (partially summarized)	Approval date	Manufac-tured/ Imported
1	Remsima Inj. 100mg	Celltrion Pharm, Inc.	Remicade (Infliximap)	Rheumatoid arthritis, psoriasis, etc.	2012-07-20	Manufactured
2	Herzuma Inj. 150mg	Celltrion Pharm, Inc.	Herceptin Inj. (Trastuzumab)	Breast cancer, gastric cancer	2014-01-15	Manufactured
3	Herzuma Inj. 440mg					Manufactured
4	SciTropin A 5mg	SciGen Korea Co.,Ltd	Genotropin (Somatropin)	Growth failure of children, etc.	2014-01-28	Imported
5	SciTropin A 10mg					Imported
6	Davictrel Inj. 25mg	Hanwha Chemical Co.	Enbrel (Etanercept)	Rheumatoid arthritis, psoriasis, etc.	2014-11-11 (Withdrawn on 2015-09-30)	Manufactured
7	Brenzys 50 mg Prefilled Syringe → (name changed to) Etoloce 50 mg solution for injection in pre-filled syringe	Samsung Bioepis	Enbrel (Etanercept)	Rheumatoid arthritis, psoriasis, etc.	2015-09-07	Imported (developed in Korea)
8	Basaglar Cartridge	Lilly Korea	Lantus (Insulin	Diabetes	2015-11-25	Imported

No.	Product name	Company	Reference drug (Ingredient)	Efficacy/Effectiveness (partially summarized)	Approval date	Manufac-tured/ Imported
	100unit/mL(Insulin Glargine, Recombinant)		glargine)		(Withdrawn on 2019-09-26)	
9	Basaglar Kwikpen 100Unit/mL(Insulin Glargine, Recombinant)				2015-11-25	Imported
10	Renflexis Inj. 100 mg → (name change) Remaloce 100 mg powder for concentrate for solution for infusion	Samsung Bioepis	Remicade (Infliximap)	Rheumatoid arthritis, ulcerative colitis, etc.	2015-12-04	Imported (developed in Korea
11	Truxima Inj.	Celltrion Pharm, Inc.	MabThera Inj. (Rituximab)	Rheumatoid arthritis, lymphoma, etc.	2015-07-16 2016-11-16 (Switched for domestic use)	Manufactured
12	Hadlima Prefilled Syringe 40 mg → (name changed to) Adalloce 40 mg solution for injection in pre-filled syringe	Samsung Bioepis	Humira Inj. 40 mg (Adalimumab)	Rheumatoid arthritis, psoriatic arthritis, etc.	2017-09-20	Imported (developed in Korea
13	Samfenet 150 mg powder for concentrate for solution for infusion	Samsung Bioepis	Herceptin Inj. (Trastuzumab)	Breast cancer, gastric cancer	2017-11-08	Imported (developed in Korea
14	Glarzia Prefilled Pen	GC Pharma	Lantus (Insulin glargine)	Diabetes	2018-03-07	Imported
15	Glarzia Prefilled Pen	LG Chem Co., Ltd.	Enbrel (Etanercept)	Rheumatoid arthritis, psoriasis, etc.	2018-03-16	Manufactured
16	Eucept Prefilled Syringe Inj.					Manufactured
17	NESBELL 20	Chong Kun Dang pharm.	Nesp (Darbepoetin alpha)	Anemia in patients with chronic renal failure, etc.	2018-11-29	Manufactured
18	NESBELL 30					Manufactured
19	NESBELL 40					Manufactured
20	NESBELL 60					Manufactured
21	NESBELL 120					Manufactured
22	Etoloce 50 mg solution for injection in pre-filled pen	Samsung Bioepis	Enbrel (Etanercept)	Rheumatoid arthritis, psoriasis, etc.	2019-08-19	Imported (developed in Korea
23	Terrosa Cartridge Inj.	Daewon Pharm. Co., Ltd	Forsteo (Teriparatide)	Osteoporosis	2019-10-29	Imported
24	Panpotin Prefilled Syringe 2000IU	PanGen Biotech Inc.	Eprex (Recombinant human erythropoietin)	Anemia in patients with chronic renal failure	2019-11-28	Manufactured
25	Panpotin Prefilled Syringe 4000IU					Manufactured
26	Adalloce 40 mg solution for injection in pre-filled pen	Samsung Bioepis	Humira Inj. 40 mg (Adalimumab)	Rheumatoid arthritis, psoriatic arthritis, etc.	2020-07-03	Imported (developed in Korea
27	Ogivri Injection 150mg	Alvogen Korea Co., Ltd.	Herceptin Inj. (Trastuzumab)	Breast cancer, gastric cancer	2020-08-26	Imported
28	Samfenet 440 mg powder for concentrate for solution for infusion	Samsung Bioepis	Herceptin Inj. (Trastuzumab)	Breast cancer, gastric cancer	2020-10-14	Imported (developed in Korea

No.	Product name	Company	Reference drug (Ingredient)	Efficacy/Effectiveness (partially summarized)	Approval date	Manufac-tured/ Imported
29	Bemfola prefilled pen.(follitropin alfa)	YooYoung Pharmaceutical Co., Ltd.	Gonal-F Pen Inj. (Follitropin-alfa)	Ovarian hyperstimulation, anovulation	2020-10-29	Imported
30	Onbevzi inj.	Samsung Bioepis	Avastin (Bevacizumab)	Metastatic colorectal cancer, etc.	2021-03-11	Imported (developed in Korea
31	Zyrabev	Pfizer Korea Ltd.	Avastin (Bevacizumab)	Metastatic colorectal cancer, etc.	2021-05-17	Imported
32	SciTropin A 15mg	SciGen Korea Co., Ltd	Genotropin (Somatropin)	Growth failure in children, etc.	2021-07-09	Imported
33	Yuflyma PFS 40mg/0.4mL	Celltrion Pharm, Inc.	Humira 40mg/0.4mL (Adalimumab)	Rheumatoid arthritis, psoriatic arthritis, etc.	2021-10-15	Imported (developed in Korea
34	Yuflyma 40mg/0.4mL					Imported (developed in Korea
35	Bonsity pen injection	Pharmbio Korea Inc.	Forsteo (Teriparatide)	Osteoporosis	2021-11-16	Imported

* Detailed approval information (efficacy/effectiveness, usage/dosage, and precautions for use) is available at http://nedrug.mfds.go.kr.

3.3. Approval Status of Advanced Biological Products

1) Approval Status of Cell Therapy Products

With the enactment of the 'Act on the Safety of and Support for Advanced Regenerative Medicine and Advanced Biological Products' (hereinafter referred to as the Advanced Regenerative Bio Act), the approval system, previously centered on synthetic drugs and traditional biopharmaceuticals, was reorganized based on the characteristics of advanced biological products.

From August 28th, 2020, 14 out of 15 previously approved cell therapy products were re-approved as advanced biological products in 2021. The one excluded product was a product that was withdrawn voluntarily due to the enforcement of the Advanced Remunerative Bio Act.

By considering the purpose of the enactment (such as reflecting the quality control elements required by the Advanced Renewable Bio Act), and by collecting opinions from and providing close consultation support to the industries, all items were re-approved within the deadline set by the Act (August 27th, 2021).

Table 44. List of Approved Cell Therapy Products (2001~2021)

No.	Manufac-tured/ Imported	Product name	Ingredient	Company	First Approval date	Re-approved date	Efficacy/Effectiveness (partially summarized)	Re-marks
1	Manufac-tured	Chondron	RMS autologous cartilage-derived chondrocyte	Cellontech Co., Ltd	2001-01-30	2021-08-26	Treatment of focal cartilage defect in knee joint (defect size: not more than 15 ㎠ in single lesion, not more than 20 ㎠ in multiple lesion)	
2	Manufac-tured	Holoderm	Autologous keratinocyte	Tego Science, Inc	2002-12-10	2021-08-27	Creation of functional epidermis by transplanting to 1. The burn where second degree burn takes not less than 30% of the body surface area 2. The burn where third degree burn takes not less than 10% of the body surface	
3	Manufac-tured	Kaloderm	Allogeneic keratinocyte	Tego Science, Inc	2005-03-21	2021-08-27	1. Promoting re-epithelization of deep second degree burn 2. Promoting wound healing of diabetic foot ulcer that has good blood supply and does not have findings of infection	
4	Manufac-tured	Keraheal	Basol autologous keratinocyte	Biosolution Co., Ltd.	2006-05-03	2021-08-25	Creation of functional epidermis by transplanting to 1. The burn where second degree burn takes not less than 30% of the body surface area 2. The burn where third degree burn takes not less than 10% of the body surface	
5	Manufac-tured	Immuncell-LC	LC autologous blood origin T lymphocyte	GC Cell	2007-08-06	2021-08-27	Adjuvant therapy for patients whose tumor has been removed after curative resection for hepatocellular carcinoma (operation, radio frequency ablation, percutaneous ethanol injection therapy)	
6	Manufac-tured	RMS Ossron	Autologous osteoblast	Cellontech Co.,Ltd	2009-08-26	2021-08-06	Promoting local bone formation	

No.	Manufac-tured/ Imported	Product name	Ingredient	Company	First Approval date	Re-approved date	Efficacy/Effectiveness (partially summarized)	Re-marks
7	Manufac-tured	Queencell	Minimally manipulated autologous adipose tissue-derived fat cell	Anterogen. Co., Ltd	2010-03-26	2021-06-09	Improvement of subcutaneous fat defect	
8	Manufac-tured	CureSkin Inj.	Autologous dermal fibroblast	S.Biomedics Co., Ltd.	2010-05-11	2021-07-29	Improvement of dented scar area came from the acne treatment process	
9	Manufac-tured	Hearticellgram - AMI	Autologous adipose-derived mesenchymal stem cell	Pharmicell Co., Ltd.	2011-07-01	2021-08-26	Improvement of left ventricular ejection fraction in patients who had reperfused acute myocardial infarction by coronary angioplasty within 72 hours after chest pain	
10	Manufac-tured	CARTISTEM	Allogenic umbilical cord blood-derived mesenchymal stem cell	MEDIPOST Co., Ltd.	2012-01-18	2021-08-19	Treatment of knee cartilage defects in patients with degenerative or repetitive traumatic osteoarthritis (ICRS grade IV)	
11	Manufac-tured	Cupistem	Autologous adipose-derived mesenchymal stem cell	Anterogen. Co., Ltd	2012-01-18	2021-08-24	Treatment of fistula caused by the Crohn's disease	Orphan drugs
12	Manufac-tured	Neuronata ® inj.	Autologous adipose-derived mesenchymal stem cell	Corestem Inc.	2014-07-30	2021-08-27	Alleviate the disease progression rate of amyotrophic lateral sclerosis in combination with riluzole	Orphan drugs
13	Manufac-tured	Keraheal-Allo	Bosol allogeneic keratinocyte	Biosolution Co., Ltd.	2015-10-16	2021-08-25	Promoting re-epithelization of deep second degree burn	
14	Manufac-tured	Rosmir	Tego autologous fibroblast	Tego Science,Inc	2017-12-27	2021-08-24	Improvement of moderate to severe nasojugal groove	
15	Manufac-tured	Cartilife	Basol autologous cartilage-derived chondrocyte	Biosolution Co., Ltd.	2019-04-24	2021-07-22	Treatment of knee cartilage defect (ICRS grade III or IV, defect area 2 to 10 ㎠)	

* Detailed approval information (efficacy/effectiveness, administration/dosage, and precautions for use) is available at http://nedrug.mfds.go.kr.

2) Approval Status of Gene Therapy Agents

In 2021, 3 imported gene therapy agents were approved. 2 were new drugs (including orphan drugs) and 1 was an orphan drug (excluding 2

new orphan drugs). Pursuant to the 'Act on the Safety of and Support for Advanced Regenerative Medicine and Advanced Biological Products', they were approved as advanced biological products.

'Kymriah (Tisagenlecleucel)' (Novartis Korea, approved on Mar. 5, 2021) is an autologous, immuno-cellular cancer therapy which involves repro -gramming a patient's own T cells with a transgene encoding a chimeric antigen receptor(CAR) to identify and eliminate. It was approved as a new orphan drug to treat persons 25 years of age or younger with relapsed or refractory B-cell acute lymphoblastic leukemia (ALL), and adult patients who relapsed or refractory diffuse large B-cell lymphoma (DLBCL).

'Zolgensma (Onasemnogene_abeparvovec)' (Novartis Korea, approved on May 28, 2021) was approved as an orphan drug to treat spinal muscular atrophy with a biallelic mutation in the Survival Motor Neuron (SMN1) gene. This drug is a treatment for the adeno-associated virus (AAV9) platform containing the SMN1 gene. It exists as an episome in host cells and stably expresses the SMN protein, relieving symptoms of spinal muscular atrophy and prolonging survival.

'Luxturna (Galcanezumab, recombinant protein, boretizinepavovec)' (Novartis Korea, approved on Sep. 9, 2021) is a gene therapy product that restores the visual circuit by transducing complementary DNA (cDNA) that encodes normal human RPE65 protein into the retinal pigment epithelium (RPE) of the patient. It was approved as an orphan drug to treat adults and children who have lost sight due to inherited retinal dystrophy (caused by a protein biallelic RPE65 mutation) and have sufficient viable retinal cells.

The enforcement of the Advanced Regenerative Bio Act made it possible to provide rapid treatment opportunities to patients with a rare or incurable diseases. As a full-cycle safety management system based on the characteristics of advanced biological products is in place, the products may be used with greater confidence.

Table 45. List of Approved Gene Therapy Agents (~ 2021)

No.	Manufac-tured/ Imported	Product name	Ingredient	Company	Approval date	Efficacy/Effectiveness	Re-marks
1	Imported	Kymriah	Tisagenlecleucel	Novartis Korea	2021-03-05	1. Treatment of leukemia relapsed after transplantation or secondary relapse and subsequent relapsed leukemia or refractory B-cell acute lymphoblastic leukemia (ALL) in pediatric patients up to 25 years of age and young adult patients 2. Treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after two or more systemic therapies	New orphan drugs
2	Imported	Zolgensma	Onasemnogene_ abeparvovec	Novartis Korea	2021-05-28	Patient with Spinal Muscular Atrophy (SMA) with a biallelic mutation in the Survival Motor Neuron 1 (SMN1) gene falling under any of the following: - Clinically diagnosed with Type 1 - Three or less copy numbers of Survival Motor Neuron 2 (SMN2) gene	New orphan drugs
3	Imported	Luxturna	Voretigene neparvovec	Novartis Korea	2021-09-09	Treatment of adults and children who have lost vision due to inherited retinal dystrophy caused by biallelic RPE65 mutation and have sufficient viable retinal cells	orphan drugs

4

Approval Status of Herbal (Oriental) Medicines

4. Approval Status of Herbal (Oriental) Medicines

In 2021, 20 herbal (oriental) medicines were approved, decreasing by 25.5%, 54.5%, 52.4%, 64.3% and 69.7% compared to 2016 (31 items), 2017 (44 items), 2018 (42 items), 2019 (56 items) and 2020 (64 items) respectively (see Table 46).

Analyzing by review type, 1 new drug and 3 drugs that require data submission (3 new dosage forms) were approved. Additionally, 4 items that were approved based on equivalence data (e.g., Bioequivalence test, etc.), an item that was exempt from submitting safety and efficacy data (since the drugs already exist in a foreign compendium), 6 items based on the prescriptions in Korean traditional herbal medicine book, 3 drug substances, and 2 medicinal herbs were approved.

Table 46. Approval Status of Herbal (Oriental) Medicines, etc., by Review Type in 2021

(Unit: Number of items)

<table>
<tr><th>Type</th><th colspan="3">Review Type</th><th colspan="2">Number of approved items</th></tr>
<tr><td>1</td><td rowspan="2">New drugs (1)</td><td colspan="2">New drugs</td><td colspan="2">1</td></tr>
<tr><td>2</td><td colspan="2">New orphan drugs</td><td rowspan="2">Orphan drugs (0)</td><td colspan="2">0</td></tr>
<tr><td>3</td><td colspan="3">Orphan drugs</td><td colspan="2">0</td></tr>
<tr><td>4</td><td colspan="4">Drugs that require data submission</td><td colspan="2">3</td></tr>
<tr><td>4-1</td><td colspan="4">Incrementally modified drugs</td><td colspan="2">0</td></tr>
<tr><td>4-2</td><td rowspan="7">Drugs that require data submission</td><td colspan="2">New composition and specification</td><td rowspan="7">3</td><td>0</td></tr>
<tr><td>4-3</td><td colspan="2">Change in strength</td><td>0</td></tr>
<tr><td>4-4</td><td colspan="2">New drug efficacy/effectiveness, mode of administration/dosage</td><td>0</td></tr>
<tr><td>4-5</td><td colspan="2">New route of administration</td><td>0</td></tr>
<tr><td>4-6</td><td colspan="2">New dosage form</td><td>3</td></tr>
<tr><td>4-7</td><td colspan="2">Literature evidence other than Korean traditional herbal medicine books</td><td>0</td></tr>
<tr><td>4-8</td></tr>
</table>

Type	Review Type		Number of approved items	
5	Proof of equivalence		4	
6	Others	Exempted from safety/efficacy data submission	12	1
		Prescriptions in Korean traditional herbal medicine books		6
		Drug substances		3
		Meidicinal herbs		2

When categorized according to the drug classification criteria, all approved items were manufactured, and includes 5 ETC, 10 OTC, 3 drug substances and 2 medicinal herbs (see Table 47).

Table 47. Approval Status of Herbal (Oriental) Medicines, etc., in 2021

(Unit: Number of items)

Type	Category	Total	Item approval			
			ETC	OTC	Drug substan-ces	Medicinal Herbs
Total		20	5	10	3	2
Herbal (oriental) medicine, etc.	Manufactured	20	5	10	3	2
	Imported	0	0	0	0	0

4.1 Approval Status of New Herbal (Oriental) Medicines

No new herbal (oriental) medicine was approved from 2014 to 2020. However, in 2021, one new domestically manufactured herbal (oriental) medicine was approved in 2021 (see Table 48).

Table 48. Approval Status of New Herbal (Oriental) Medicines by Year (2010~2021)

	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
Manufactured	0	0	0	0	0	0	0	0	0	0	0	1
Imported	2	0	0	1	0	0	0	0	0	0	0	0

‘BRONPASS(Prepared Rehmannia Root·Moutan Root Bark·Schisandra Fruit·Asparagus Tuber·Scutellaria Root· Apricot Kernel·Stemonae Radix soft ext.(1.4～1.7→1)·Corn starch mixed dried products(4.8:1))’ (Hanlim Pharm. Co., Ltd., approved on Apr. 9, 2021) is a ‘domestically developed new drug.’ Among the active ingredients, stemona root does not have any previously approved use cases. The product was developed to improve acute bronchitis (see Table 49).

Table 49. Approval Status of New Drugs in 2021 (Herbal (oriental) medicines)

No.	Manufac-tured/ Imported	Product name	Company	Approval date	Detailed classification	Efficacy/Effectiveness (partially omitted)
1	Manufac-tured	BRONPASS(Prepared Rehmannia Root·Moutan Root Bark·Schisandra Fruit·Asparagus Tuber·Scutellaria Root· Apricot Kernel·Stemonae Radix soft ext.(1.4～1.7→1)·Corn starch mixed dried products(4.8:1))	Hanlim Pharm. Co., Ltd.	2021-04-09	Miscellaneous respiratory drugs	Improvement of acute bronchitis

4.2 Approval Status of Herbal (Oriental) Medicines that require Data Submission

In 2021, 3 new formulations were approved for herbal (oriental) medications that require data submission (see Table 50).

Table 50. Approval Status of Drugs that require Data Submission in 2021

Review Type of Drugs that require data submission	Number of approved items
New dosage form	3
Total	3

1) New Dosage Form with the Same Rout of Administration (3 items)

There were three new dosage forms (all manufactured) that were approved: a granule item that was developed into a soft extract, a powder agent that was developed into a gel product, and a soft capsule that was developed into a dry extract tablet (see Table 51).

‘Dimagen Soft Ext. (Banhasasimtang)’ (JungWoo Pharmaceutical Company, approved on Feb. 5, 2021) was developed by changing the dosage form of ‘Dimagen Ext. Granules (Banhasasimtang)’ to a soft extract product, and is used to treat gastrointestinal diseases and stomatitis, etc.

‘Madecassol Gel (Centella titrated ext.)’ (DongKook Pharmaceutical Co., Ltd., approved on Feb. 9, 2021) was developed by changing the dosage forms of ‘Madecassol Ointment’ and ‘Madecassol Powder (Centella titrated ext.)’ (for external use) from powder and ointment form to gel form. It was developed as an auxiliary partial treatment for wounds and skin ulcers.

‘Thiliskan soft Cap. (Milk Thistle Fruit Dry Extract)’ (Neo Bio korea Pharm Co., Ltd., approved on Dec. 13, 2021) was developed by changing the dosage form of ‘Siliman Soft Capsule' into a dry extract tablet, and is used to treat toxic liver disease, chronic hepatitis, and cirrhosis.

Table 51. Approval Status of Drugs with New Dosage Form (same route of administration) that require Data Submission in 2021

No.	Manufac-tured/ Imported	Product name	Company	Approval date	Detailed classification	Active ingredients
1	Manufac-tured	Dimagen Soft Ext. (Banhasasimtang)	JungWoo Pharmaceutical Company	2021-02-05	Miscellaneous digestive system drugs	Ginseng, licorice, scutellaria, jujube, dried ginger, coptis, pinellia
2	Manufac-tured	Madecassol Gel (Centella titrated ext.)	DongKook Pharmaceutical Co., Ltd.	2021-02-09	Miscellaneous drugs for the function of tissue cells	Centella titrated ext.
3	Manufac-tured	Thiliskan soft Cap. (Milk Thistle Fruit Dry Extract)	Neo Bio korea Pharm Co., Ltd.	2021-12-13	Liver disease agent	Dried Milk Thistle Fruit Extract

4.3 Approval Status of Other Herbal (Oriental) Medicines

Among the other herbal (oriental) medicines approved in 2021, there were 4 ETC drugs that were developed with 3 ingredients manufactured in Korea.

Two items including ‘G-maco Mini Soft Cap. 2g (Omega-3-Acid Ethyl Ester 90)’ (Kuhnil Biopharm. Co., Ltd. approved on Mar. 9, 2021) were approved as generic drugs of ‘Omacor mini Soft Capsule (Omega-3-Acid Ethyl Esters 90)’. The product is a dietary supplement to reduce elevated triglyceride levels in patients with endogenous hypertrigly-ceridemia.

‘SOFM L inj’ (Dai Han Pharm. Co., Ltd., approved on Aug. 26, 2021) is a combination formulation that contains refined fish oil (containing High-unit omega-3 fatty acids), refined olive oil, refined soybean oil, and medium-chain triglycerides. It provides energy, essential fatty acids, and omega-3 fatty acids to patients who require non-oral nutrition therapy.

‘Pentonus Syrup(Pelargonium sidoides 11% ethanol Extract(1→8-10), glycerin mix.(8:2))’ (Hanpoong Pharmaceutical Co., Ltd., approved on Sep. 23, 2021) is a generic drug of Umckamin Syrup (Pelagonium sidoides 11% ethanol extract) from the redesignation of new drug ingredients of syrups containing Pelargonium sidoides (January 2021). It is used to treat acute bronchitis.

There were 7 OTC drugs that were developed with 7 ingredients manufactured in Korea among the other herbal (oriental) medicines approved in 2021. One item was exempted from submitting safety and efficacy data, and 4 soft extract formulations and 2 tablets were approved based on the prescription in the Korean traditional herbal medicine book.

‘Plain Tab. (Dangguisusan)' (KBPharm Inc., approved on Feb. 8, 2021) is an item formulated with a new dosage form, but has the same administration route as what is listed in the Korean traditional herbal medicine book (Donguibogam) (excluding special formulations such as sustained-release tablets). It is used to treat swelling and pain due to bruises.

‘Kyungbang Naesosan Soft Ext.(Mix Soft Extract)' (KBPharm Inc., approved on Apr. 15, 2021) is an item formulated with a new dosage form, but has the same administration route (Soft extract) as what is listed in the Korean traditional herbal medicine book (Donguibogam). It was approved as a mix soft extract.

‘Ceremin Tab.’ (JungWoo Pharmaceutical Company, approved on Jun. 7, 2021) is exempted from submitting safety and efficacy data as they already exist in a foreign compendium pursuant to the ‘Regulation on Approval and Notification of Herbal (Oriental) Medicines, etc.’ It is used to improve mental function deterioration accompanying symptoms such as reduced concentration, memory loss, and dizziness (arteriosclerosis symptoms).

‘Hanpoong Dragan Tab. (Donguibogam Yongdamsagantang)’ (Hanpoong Pharmaceutical Co., Ltd., approved on Nov. 8, 2021) is an item formulated with a new dosage form, but has the same administration route (tablet) as what is listed in the Korean traditional herbal medicine book (Donguibogam). It is used to treat symptoms of bitter taste in the mouth due to excessive stress.

‘Hanpoong Wiga-S Soft extract (Donguibogam Wiryeongtang)’, ‘Hanpoong Hwamiyeon Soft Extract (Bangyakhappyon Gamigwibitang)’, and ‘Hanpoong Danggwisusan Soft Extract’ (Hanpoong Pharmaceutical Co., Ltd., approved on Nov. 8, 2021) are listed in oriental medicine books. The drugs are items formulated with new dosage forms, but has the same administration route (Soft Extract) as what is listed in the Korean traditional herbal medicine book (Donguibogam). They are used to treat indigestion, vomiting, diarrhea, abdominal pain, irregular menstruation due to stress and depression, swelling, and pain due to bruising.

4.4 Approval Status of Herbal Substances and Medicinal Herbs

There were 3 items approved as drug substances for herbal (oriental) medicines, and 2 items - Guscutae semen preparata cum vinum, Polygoni multiflori radix glycinesoga sieb - were approved as medicinal herbs (see Table 52).

Table 52. Approval Status of Herbal (Oriental) Medicine, etc. (Drug substances, medicinal herbs)

No.	Manufactured / Imported	Product name	Company	Approval date	Remarks
1	Manufactured	Bolak Agastachis Herba·Curcuma Root·Coptis Rhizome·Clove 30 % Ethanol Fluid Extracts(1→1)	Bolak company limited	2021-01-20	Drug substances
2	Manufactured	Bolak Poncirus Immature Fruit·Corydalis Tuber 30 % Ethanol Fluid Extracts(1→1)	Bolak company limited	2021-02-15	Drug substances
3	Manufactured	Bolak Cinnamon Bark Dry Extract(16~26→1)	Bolak company limited	2021-12-15	Drug substances
4	Manufactured	Guscutae semen preparata cum vinum	(Corporation) Omniherb	2021-08-02	Medicinal herbs
5	Manufactured	Polygoni multiflori radix glycinesoga sieb	(Corporation) Omniherb	2021-08-02	Medicinal herbs

* Detailed approval information (efficacy/effectiveness, administration/dosage, and precautions for use) is available at http://nedrug.mfds.go.kr.

Appendix	Status of the Departments in Charge of Civil Petition Regarding Pharmaceuticals, etc.

Table 53. Status of the Departments in Charge of Civil Petition Regarding Pharmaceuticals, etc. (As of April 2022)

Category	Department	Pharmaceuticals related services
Director for Approval Management		·Approval of drugs for manufacturing/marketing and import ·Management related to drug review and approval system ·Registration of DMF ·Classification of drugs ·Review of range of pharmacy preparations and medical institution dispensary preparations ·Improvement of approval/review system ·Enactment/amendment of guidelines related to approval ·General management of preliminary review of approval/ notification
Director for Noval Product Approval		·Approval of biologics, recombinant protein products, advanced biological products and quasi-drugs for manufacturing/ marketing and import ·Approval of manufacture and importation by product type and classification of medical devices (only applicable to Class I devices subject to approval and Class III/IV devices) ·Classification and approval of products in which drugs, quasi-drugs and medical devices are physically/chemically combined (combination products) ·Operation of approval system for biopharmaceuticals, quasi-drugs, medical devices and combination products ·Orders of re-review on medical devices
Pharmaceutical Safety Bureau	Pharmaceutical Policy Division	·Designation of orphan drugs ·Registration and management of the drug patent list ·Operation of drug patent-approval linkage (approval of priority of sales, etc.)
	Pharmaceutical Management Division	·Drug labeling ·Renewal of drugs
	Pharmaceutical Safety Evaluation Division	·Re-evaluation and re-review of drugs ·Risk management plan
	Pharmaceutical Quality Division	·GMP evaluation and guidance of drugs ·Inspection of drug substances (DMF)
	Clinical Trials Policy Division	·Approval of clinical trial plans ·Inspection of clinical trials ·Management of institutions for clinical and non-clinical (GLP) trials.

Category	Department		Pharmaceuticals related services
	Narcotics Policy Division		·Approval of manufacture and import/export businesses and products of narcotic drugs. ·Quality management of narcotic drugs ·Designation of temporary narcotics
	Narcotics Management Division		·Follow-up management of narcotics
National Institute of Food and Drug Safety Evaluation	Pre-Submission Consultation Division		·Pre-submission consultation for the approval of clinical trial plan for new drugs and drugs that are subjects of expedited review (including biologics, recombinant protein products and herbal medicinal preparations) ·Pre-submission consultation on the approval for new drugs and drugs that are subject of expedited review ·Pre-submission consultation on the approval for clinical trial plan for medical devices that are subjects of expedited reivew (excluding software-based medical devices and in vitro diagnostic devices) ·Pre-submission consultation on the approval for medical devices that are subjects of expedited review ·Pre-submission consultation and review support for clinical statistics data ·Operation of a preliminary review system for drugs, etc. ·Support commercialization of drugs and medical devices under the jurisdiction ·Enactment/amendment of instructions/guidelines related to pre-submission consultation ·Support international cooperation such as operating the Asia-Pacific Economic Cooperation(APEC) Harmonization Center
	Expedited Review Division of medicine and medical device		·Review of applications for designation of drugs (including biologics, recombinant protein products, herbal (oriental) medicines) that are subjects of expedited review ·Review of applications for designation of medical devices (excluding software-based medical devices and in vitro diagnostic devices) that are subjects of expedited review ·Expedited review of quality and safety/efficacy of drugs that are designated for expedited review ·Expedited review of technical documents and clinical trial data of medical devices that are designated for expedited review ·Preliminary review of drugs and medical devices under the jurisdiction (excluding previously approved items) ·Enactment/amendment of instructions/guidelines related to expedited review
	Drug Evaluation Department	Pharmaceutical standardization Division	·Review of registration data of drug substances (excluding substances of new drugs) ·Generic drug quality review ·Review the standards and test methods for the following

Category	Department		Pharmaceuticals related services
			drugs 710 Drugs for compounding 731 Preservatives 741 Capsules 799 Drugs not classified separately and not intended for treatment (not including safety and efficacy) · Review of equivalence test data on the revision (addition) of the active substance manufacturer without changes in the manufacturing method.
		Cardiovascular and Neurology Products Division	110 Drugs for central nervous system 120 Drugs for peripheral nervous system 130 Drugs for sensory organs 190 Miscellaneous drugs for nervous system and sensory organs 210 Circulatory system drugs 264 Drugs for pain-relieving, antipruritic, convergence, anti-inflammatory 300 Metabolic drugs (excluding miscellaneous metabolic drugs (390)) 799 Drugs not classified separately and not primarily used for treatment 800 Narcotics ·Safety/efficacy review ·Review of clinical trial plans ·Preliminary review ·Re-evaluation, re-review, and review of RMP periodic report
		Oncology and Antimicrobial Products Division	140 Antiallergic drugs 220 Respiratory organ drugs 240 Hormone drugs (including anti-hormonal agents) 250 Urogenital and anal organ drugs 260 Dermatologic drugs (excluding 264, 267, and 268) 290 Miscellaneous drugs for individual organs 400 Drugs for functional activation of tissue cells 600 Anti-pathogenic biological drugs 720 Drugs for diagnosis 730 Drugs for public hygiene ·Safety/efficacy review ·Review of clinical trial plans ·Preliminary review ·Review of re-evaluation of re-review data
		Advanced Drug Quality Division	·Review of the quality of new drugs, orphan drugs, drugs that require data submission, etc. ·Review of registration data of drug substances (new

Category	Department		Pharmaceuticals related services
			substances and its salts) ·Quality review of clinical trial plans ·Quality review of drugs included in combination products ·Quality review of radiopharmaceuticals ·Preliminary review on quality of drugs under the jurisdiction ·Review of equivalence test data on the revision (addition) of the active substance manufacturer without changes in the manufacturing method for the drugs under the jurisdiction
		Bioequivalence Evaluation Division	·Review of bioequivalence test plan ·Review of bioequivalence test result report ·Review of reliability of bioequivalence test ·Re-evaluation of bioequivalence test ·Review of drug equivalence test result report (approval/notification of manufactured(imported) items (post-approval/notification changes included). ·Review of drug equivalence test result report (approval/notification) ·Safety/efficacy review and review of clinical trial plans of digestive system drugs (230) Safety/efficacy review and review of clinical trial plans of miscellaneous metabolic drugs (390) ·Preliminary review ·Review of re-evaluation of re-review result report ·Periodic reports and results of risk management plan, and PSUR reviews
Biopharma-ceuticals and Herbal Medicine Bureau	Biological Product Policy Division (Advanced Biological Product TF)		GMP evaluation for advanced biological products ·GMP evaluation ·Review of re-evaluation/re-review/review of risk management plan data
	Biopharmaceutical Quality Management Division		·GMP evaluation and guidance for manufacturers and manufactured/imported items such as biopharmaceuticals ·Inspection of active pharmaceutical ingredients (DMF) that are subjects of notification of human placenta-derived drugs ·Re-review and re-evaluation of biopharmaceuticals ·Risk management plan
	Herbal Medicine Policy Division		·Preliminary GMP evaluation for herbal medicines
	Cosmetics Policy Division		·GMP evaluation for cosmetics, etc.
	Quasi-Drug Policy Division		·GMP evaluation for quasi-drug
NIFDS	Biopharm-ceuticals	Biologics Division	Biologics and human placenta-derived drugs ·Quality and safety/efficacy review

Category	Department		Pharmaceuticals related services
	and Herbal Medicine Evaluation Department		·Review of clinical trial plans ·Preliminary review ·Review of re-evaluation and re-review result report
		Recombinant Protein Products Division	Recombinant Protein Products ·Quality and safety/efficacy review ·Review of clinical trial plans ·Preliminary review ·Review of re-evaluation and re-review result report
		Cell and Gene Therapy Products Division	Advanced Biological products ·Quality and safety/efficacy review ·Review of clinical trial plans ·Preliminary review ·Review of re-evaluation and re-review result report
		Herbal Medicinal Products Division	Herbal (oriental) medicines, etc. ·Quality and safety/efficacy review ·Review of drug equivalence (including bioequivalence test) ·Review of clinical trial plans ·Preliminary review ·Review of re-evaluation and re-review data
		Cosmetics Evaluation Division	Functional cosmetics ·Quality and safety/efficacy review ·Evidental data review of cosmetics labelling/advertisement Quasi-drugs ·Quality and safety/efficacy review ·Preliminary review ·Review of re-evaluation data

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