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2020 Drug Approval Report

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Ministry of Food and Drug Safety

Director for Approval Management

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General Information on Drug Approval/Notification Status (Overall) in 2020

1. General Information on Drug Approval/Notification Status (Overall) in 2020

This 2020 Drug Approval Report is issued to support the systematization and efficiency of the establishment/enforcement of related regulations and drug approval/notification, along with product development by sharing the approval/notification status of all drugs in line with the 2019 Drug Approval Report.

1.1. General Information

In 2020, a total of 3,496 items were approved and notified as shown in Table 1, which include chemical drugs, biopharmaceuticals and herbal medicinal preparations. The total number of items decreased by 43.5% compared to the previous year (2,691 items), and in particular, the number of approved and notified items for manufacturing decreased sharply by 45.0% (2,712 items). This seems to be the result of the decrease in the number of generic drug approvals/notifications, which had sharply increased in 2019 due to the submission of consigned co-bioequivalence test data. The number was increased by 1.4 times from the previous year, 2018.

Table 1. Outline of Drug Approval/ Notification Status (2018-2020)

(Unit: number of items)

Year	Total	Approval	Notification	Headquarters	Regional office	Manufactured	Imported	Drug product	Drug substance (excluding herbal substances)	Herbal substances	Drug product	
											Prescribed	OTC
'20	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 herbal substances (198)		excluding herbal substances (198)		excluding herbal substances (198)		excluding herbal substances (%)				
		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%			
'19	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 herbal substances (1307)		excluding herbal substances (1307)		excluding herbal substances (1307)		excluding herbal substances (%)				
		3,684 (75.5%)	1,196 (24.5%)	622 (12.7%)	4,25 (87.3%)	4,728 (96.9%)	152 (3.1%)	98.5%	1.5%			
'18	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 herbal substances (361)		excluding herbal substances (361)		excluding herbal substances (361)		excluding herbal substances (%)				
		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 (122 items), including revoked and withdrawn items and herbal substances

Among the total items (3,496 items), approved items accounted for 66.3% (2,319 items) and notified items accounted for 33.7% (1,177 items). While 21.1% (738 items) were approved and/or notified by the eadquarters, 78.9% (2,758 items) were approved and/or notified by regional offices. This shows that the number of approved and notified items decreased in 2020 compared to 2019.

Domestically manufactured and marketed items accounted for 95.1% (3,323 items), whereas imported items only accounted for 4.9% (173 items). Drug products, active pharmaceutical ingredients, and herbal substances accounted for 92.4% (3,229 items), 2.0% (69 items), and 5.7% (198 items) respectively, which shows that the number of drug products and herbal substances decreased, while the number of imported items and active pharmaceutical ingredients was similar to

those in the previous year.

Drug products (97.9%) made up a significantly larger percentage than active pharmaceutical ingredients (2.1%) excluding herbal substances. Among the drug products (3,229 items), ethical-the-counter (ETC) drugs amounted to 78.2% (2,525 items) while the over-the-counter (OTC) drugs reached 21.8% (704 items).

As in 2019, domestically manufactured and marketed items took the largest share among the items approved and notified in 2020. The number of approvals and notifications of domestically manufactured and marketed items (excluding herbal substances) increased significantly in 2019 (4,728 items) compared to 2018 (1,999 items), the number decreased by 33.9% in 2020 (3,125 items) compared to the previous year. This is understood to be the effect of the decrease in the number of approved or notified generic drug submitted with the consigned(joint) bioequivalence test data.

In the case of notified items (excluding herbal substances), as a result of the introduction of the GMP pre-audit of OTC drugs on July 1, 2009, the number of notified items (753 items) in 2011 significantly decreased to almost half as compared to that of 2010 (1,530 items) and there has been no significant change. However, it increased by 1.7 times (453 items) in 2019 and decreased by 17.9% (213 items) in 2020 compared to 2019 by the decrease in the number of generic drugs.

The number of approval and notified items for herbal substances was 194 in 2020, which decreased by 85.2% (1,113 items) compared to 1,307 items in 2019, because of a decrease in the number of items by the notification from new drug manufacturers.

Table 2-1. Number of Drug Approval/ Notification by Year (Excluding Herbal Substance)

(Unit: number of items)

Category	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Approval	614	853	831	1,423	1,811	2,110	2,030	1,306	1,378	3,684	2,315 (70.2%)
(Year-on-year increase, %)	38.9%	-2.5%	71.2%	27.3%	16.6%	-3.8%	-35.7%	5.5%	167.3%	-37.2%	
Notification	1,530	753	687	787	1,118	904	815	798	743	1,196	983 (29.8%)
(Year-on-year increase, %)	-50.7%	-8.7%	14.6%	42.1%	-19.1%	-9.8%	-2.1%	-6.9%	61.0%	-17.8%	
Total	2,144	1,606	1,518	2,210	2,929	3,014	2,845	2,104	2,121	4,880	3,298
(Year-on-year increase, %)	-25.0%	-5.4%	45.6%	32.5%	2.9%	-5.6%	-26.0%	8.1%	130.1%	-32.4%	

* Excluding drugs for export and herbal substances, including revoked/withdrawn items

Table 2-2. Number of Drug Approval/ Notification by Year (Including Herbal Substance)

(Unit: number of items)

Category	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Approval	618	853	835	1,423	1,811	2,110	2,036	1,315	1,379	3,691	2,319 (66.3%)
(Year-on-year increase, %)	38.0%	-2.1%	70.4%	47.3%	16.6%	-3.5%	-35.4%	4.9%	167.7%	-37.2%	
Notification	3,479	7,269	3,898	973	1,296	2,813	1,792	1,209	1,103	2,496	1,177 (33.7%)
(Year-on-year increase, %)	107.8%	-46.3%	-75.0%	33.2%	117.1%	-36.3%	-32.5%	-8.8%	126.3%	-52.8%	
Total	4,115	8,122	4,733	2,396	3,107	4,923	3,828	2,524	2,482	6,187	3,496
(Year-on-year increase, %)	97.4%	-41.7%	-49.4%	29.7%	58.4%	-22.2%	-34.1%	-1.7%	149.3%	-43.5%	

* Excluding drugs for export, including revoked\/withdrawn items

Table 2-3. Number of Herbal Substance Notification by Year

(Unit: number of items)

Category	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Herbal substances	1,967	6,516	3,211	186	178	1,909	983	420	361	1307	194
(Year-on-year increase, %)	231.3%	-50.7%	-94.2%	-4.3%	972.5%	-48.5%	-57.3%	-14.0%	262.0%	-85.2%	
Entire notified items including herbal substances	3,497	7,269	3,898	973	1,296	2,813	1,792	1,209	1,103	2,496	1,177

* Excluding drugs for export, including revoked/withdrawn items

Figure 1-1. Number of Drug Approval and Notification (2010-2020) (Excluding Herbal Substances)

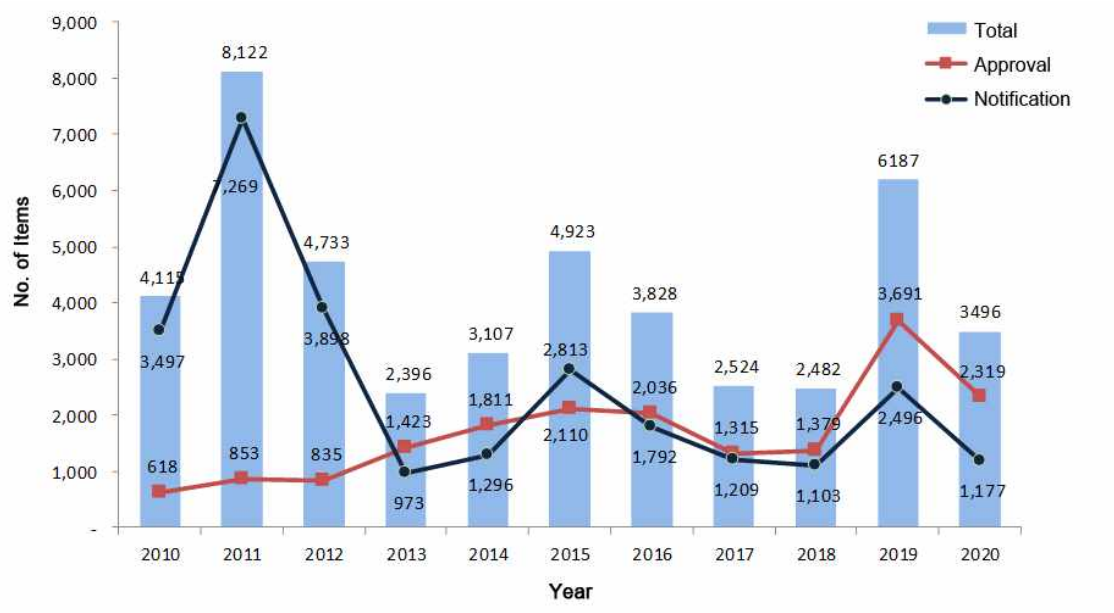

Figure 1-2. Number of Drug Approval and Notification (2010-2020) (Including Herbal Substances)

To analyze the approval and notification of medical products in 2020 in detail, the number of items approved by regional offices was 1,582 (68.3%) out of 2,315 approved items in total, which was about 2.2 times more than the number of items approved by the headquarters, which was 733 (31.7%) (Refer to Table 3-1).

This means that the number of generic drug approvals, which are subject to the approval of regional offices, was relatively higher than that of drugs requiring data submission to the headquarters. In addition, 98.7% of 1,582 drugs approved by regional offices were manufactured items (1,562 items) (Refer to Table 3-2).

Table 3-1. Drug Approval/ Notification Status by Institution in 2020

(Unit: number of items)

Category	Total	Head-quarters	Regional office
Approval	2,315 (100%)	733 (31.7%)	1,582 (68.3%)
Notification	983	0	983
Herbal substances	198	4	194
Total	3,496 (100%)	737 (21.1%)	2,759 (78.9%)

* Excluding drugs for export (122 items), including revoked and withdrawn items and herbal substances

Table 3-2. Outline of Drug Approval and Notification Status in 2020

(Unit: number of items)

<table>
<tr><th colspan="4">Domestically manufactured (3,125 items)</th><th colspan="4">Imported (173 items)</th></tr>
<tr><td rowspan="5">Drug product (3,101)
99.2%</td><td rowspan="3">ETC (2,407)
77.6%</td><td rowspan="2">Approval (2,135)</td><td>Head-quarters (576)</td><td rowspan="5">Drug product (128)
74.0%</td><td rowspan="3">ETC (118)
92.2%</td><td rowspan="2">Approval (117)</td><td>Head-quarters (97)</td></tr>
<tr><td>Regional office (1,559)</td><td>Regional office (20)</td></tr>
<tr><td>Notification (272)</td><td>Regional office (272)</td><td>Notification (1)</td><td>Regional office (1)</td></tr>
<tr><td rowspan="3">OTC (694)
22.4%</td><td rowspan="2">Approval (40)</td><td>Head-quarters (39)</td><td rowspan="3">OTC (10)
9.8%</td><td rowspan="2">Approval (3)</td><td>Head-quarters (3)</td></tr>
<tr><td>Regional office (1)</td><td>Regional office (0)</td></tr>
<tr><td>Notification (654)</td><td>Regional office (654)</td><td>Notification (7)</td><td>Regional office (7)</td></tr>
<tr><td colspan="2" rowspan="3">Active Pharmaceutical Ingredient (24)
0.8%</td><td rowspan="2">Approval (11)</td><td>Head-quarters (9)</td><td colspan="2" rowspan="3">Active Pharmaceutical Ingredient (45)
26.0%</td><td>Approval (9)</td><td>Head-quarters (9)</td></tr>
<tr><td>Regional office (2)</td><td rowspan="2">Notification (36)</td><td rowspan="2">Regional office (36)</td></tr>
<tr><td>Notification (13)</td><td>Head-quarters (0)
Regional office (13)</td></tr>
</table>

* Excluding drugs for export (122 items) and herbal substances (198 items), including revoked and withdrawn items

According to approvals and notifications by regional offices, the Gyeongin Regional Office handled the most items (40.5%, 1,116 items) among the total, followed by the Daejeon Regional Office (30.2%, 835

items) and Seoul Regional Office (15.5%, 428 items). Most of the approvals and notifications (86.2%) were handled in the Gyeongin, Seoul and Daejeon regional offices and most of the herbal substances were handled by the regional offices in Seoul (37.1%, 72 items), Daegu (21.1%, 41 items), Gwangju (20.6%, 40 items) and Daejeon (18.6%, 36 items) (Refer to Table 4).

Table 4. Details of Drug Approval and Notification Status by Regional Offices in 2020

(Unit: number of items)

Category		Approval	Notification	Herbal substances	Total
Regional office	Gyeongin	744 (47.0%)	367 (37.3%)	5 (2.6%)	1,116 (40.4%)
	Seoul	216 (13.7%)	140 (14.2%)	72 (37.1%)	428 (15.6%)
	Daejeon	443 (28.0%)	356 (36.2%)	36 (18.6%)	835 (30.2%)
	Gwangju	114 (7.2%)	79 (8.0%)	40 (20.6%)	233 (8.4%)
	Daegu	14 (0.9%)	16 (1.6%)	41 (21.1%)	71 (2.6%)
	Busan	51 (3.2%)	25 (2.5%)	0 (0%)	76 (2.8%)
Total		1,582 (100%)	983 (100%)	194 (100%)	2,759 (100%)

* Excluding drugs for export (122 items), including revoked and withdrawn items and herbal substances

Analyzing the status of manufactured and imported items of approved and notified items, the approved items took the higher proportion. In the case of manufactured items, there were more approval items (65.9%)

than notified items (34.1%) by 31.8% and, in the case of imported items, approved items (74.6%) exceeded notified items (25.4%) by 49.2% (Refer to Table 5).

Table 5. Status of Manufactured and Imported Drugs in 2020

(Unit: number of items)

Category	Total	Manufactured	Imported
Approval	2,319	2,190 (65.9%)	129 (74.6%)
Notification	1,177	1,133 (34.1%)	44 (25.4%)
Total	3,496	3,323 (100%)	173 (100%)

* Excluding drugs for export (122 items), including revoked and withdrawn items and herbal substances

According to an analysis of approved/notified drug products and active pharmaceutical ingredients, 71.1% (2,295 items) of drug products were approved, while only 29% (20 items) of active pharmaceutical ingredients (excluding herbal substances) were approved and the remaining 71% (49 items) were notified items (Refer to Table 6).

Table 6. Details of Drug Products and Active Pharmaceutical Ingredients Approval/ Notification in 2020

(Unit: number of items)

Category	Total	Drug product	Active Drug Ingredient (including herbal substances)	Active Drug Ingredient (excluding herbal substances)
Approval	2,319	2,295 (71.1%)	24 (9.0%)	20 (29.0%)
Notification	1,177	934 (28.9%)	243 (91.0%)	49 (71.0%)
Total	3,496	3,229 (100%)	267 (100%)	69 (100%)

* Excluding drugs for export (122 items), including revoked/withdrawn items

Analyzing the types of drugs among the (approved/notified) drug products, chemical drugs accounted for the majority (92.5%, 2,986 items), herbal medicinal preparations accounted for 6.4% (206 items), and biopharmaceuticals accounted for 1.1% (37 items) (Refer to Table 7).

Table 7. Classification of Chemicals, Biopharmaceuticals and Herbal Medicinal Preparations Among Drug Products in 2020

(Unit: number of items)

Category	Total[1)]	Chemicals[2)]	Biopharmaceuticals[3)]	Herbal medicinal preparations[4)]
Drug product	3,229	2,987 (92.5%)	37 (1.1%)	205 (6.4%)

1) Excluding drugs for export (122 items), including revoked/withdrawn items
2) Out of 2,989 items, 665 items were approved by the headquarters.
3) All items were approved by the headquarters.
4) Out of 205 items, 13 items were approved by the headquarters.

Among drug products, the following drugs were approved and generic drugs constituted the majority: new drugs including new orphan drugs (1.7%, 33 items); orphan drugs except new drugs (0.7%, 24 items); drugs requiring data submission (11.1%, 359 items); and generic drugs, etc. (87.1%, 2,813 items). Among the drugs requiring data submissions, 6 combination drugs developed by changing the

active substance or compounding ratio were approved as incrementally modified drugs because an improvement in their efficacy and/or usability was recognized (Refer to Table 8).

Table 8. Classification of New Drugs, Drugs Requiring Data Submission and Generic Drugs Among Drug Products in 2020

(Unit: number of items)

<table>
<tr><th rowspan="2">Category</th><th rowspan="2">Type</th><th colspan="2">New drugs</th><th>Orphan drugs</th><th colspan="2">Drugs requiring data submission</th><th colspan="3">Others</th></tr>
<tr><th>New drugs</th><th>Orphan new drugs</th><th>Orphan drugs</th><th>IMDs</th><th>Drugs requiring data submission</th><th>Herbal medicinal preparations based on herbal medicine books</th><th>(Head-quarters)</th><th>(Regional offices)</th></tr>
<tr><td rowspan="3">Drug product</td><td>Chemical 2,987</td><td>28</td><td>0</td><td>14</td><td>6</td><td>326</td><td>-</td><td>291[4]</td><td>2,322[5]</td></tr>
<tr><td>Biopharma-ceutical 37[6]</td><td>1</td><td>4</td><td>10</td><td>-</td><td>22</td><td>-</td><td>-</td><td>-</td></tr>
<tr><td>Herbal medicinal preparations 205</td><td>-</td><td>-</td><td>-</td><td>-</td><td>5</td><td>8</td><td>-</td><td>192</td></tr>
<tr><td rowspan="2">Total</td><td rowspan="2">3,229[1] (100%)</td><td>29</td><td>4[3]</td><td rowspan="2">24 (0.7%)</td><td>6</td><td>353</td><td>8</td><td>291</td><td>2,514</td></tr>
<tr><td colspan="2">33[2] (1.0%)</td><td colspan="2">359 (11.1%)</td><td colspan="3">2,813 (87.1%)</td></tr>
</table>

1) Excluding drugs for export (122 items), including revoked/withdrawn items
2) 33 items were new drugs approved in 2020, except post-approval change in new drugs (7 items) (Refer to Table 15).
3) New drug ingredients designated as both orphan drug and new drug (designated by re-review).
4) Special dosage forms, generic drugs for narcotic drugs, and items that exempt safety and efficacy review, etc.
5) Standard manufacturing items and generic drugs (excluding special dosage forms and narcotic drugs)
6) Excluding drugs for export

In addition, most of the drug products approved by the headquarters were chemical drugs (665 items, 93.0%). Regarding chemical drugs and herbal medicinal preparations, manufactured items made up most of the approvals, but in the case of biopharmaceuticals (37 items), imported products accounted for a higher ratio (78%) (Refer to Table 9).

Table 9. Items Approved by the Headquarters in 2020 (Drug products)

(Unit: number of items)

Type	Total	Manufactured	Imported
Approval by the headquarters (drug products)	715	615	100
Chemicals	665 (93.0%)	594	71
Biopharmaceuticals	37 (5.2%)	8	29
Herbal medicinal preparations	13 (1.8%)	13	0

* Excluding drugs for export, including revoked/withdrawn items

Among drug products, the approval status of ETC drugs and OTC drugs was as follows: ETC drugs were 78.2% (2,525 items), which was an approximately 3.5 times higher approval rate than OTC drugs (21.8%. 704 items). In addition, the number of approved drug products was approximately 2.5 times higher than the number of notified items (Refer to Table 10).

Table 10. Overview of Drug Approvals in 2020

(Unit: number of items)

Category	Total	Prescribed	OTC
Drug product	3,229 (100%)	2,525 (78.2%)	704 (21.8%)
Approval	2,295 (100%)	2,252 (98.1%)	43 (1.9%)
Notification	934 (100%)	273 (29.2%)	661 (70.8%)

* Excluding drugs for export (122 items) and herbal substances (198 items), including revoked and withdrawn items

According to the annual trends of item approvals and notifications above, the numbers of approved/notified items by drug type were similar in 2017 and 2018, but the total number of approved and notified items sharply increased by 2.5 times (6,187 items) in 2019 compared to 2018. And the total number decreased by 1.8 times in 2020 compared to 2019 by the decrease in approved and notified drug products and herbal substances.

To be specific, 2,525 items of ETC drugs were approved in 2020, a decrease of 39.0% compared to 2019 (4,139 items). In the case of herbal substances, 198 items were approved in 2020, a decrease of 84.9% compared to 2019 (1,307 items). On the other hand, 704 OTC drugs were approved in 2020, an increase of 5.1% compared to 2019 (670 items). The number of approvals and notifications of active pharmaceutical ingredients was similar to that of 2019 (Refer to Figure 2 and Table 11).

Table 11. Number of Approval (Notification) by Drug Type (2012-2020)

(Including Revoked and Withdrawn Items)

(Unit: number of items)

Category	2012	2013	2014	2015	2016	2017	2018	2019	2020
ETC drugs	1,002	1,669	2,090	2,289	2,280	1,573	1,514	4,139	2,525
(Year-on-year increase, %)	66.6%	25.2%	9.5%	-0.4%	-31.0%	-3.8%	173.4%	-39.0%	
OTC drugs	406	427	726	626	481	476	532	670	704
(Year-on-year increase, %)	5.2%	70.0%	-13.8%	-23.2%	-1.0%	11.8%	25.9%	5.1%	
Active pharmaceutical ingredients	110	114	113	99	84	55	75	71	69
(Year-on-year increase, %)	3.6%	- 0.9%	-12.4%	-15.2%	-34.5%	36.4%	-5.3%	-2.8%	
Herbal substances	3,215	186	178	1,909	983	420	361	1,307	198
(Year-on-year increase, %)	-94.2%	- 4.3%	972.5%	-48.5%	-57.3%	-14.0%	262.0%	-84.9%	
Total	4,733	2,396	3,107	4,923	3,828	2,524	**2,482**	**6,187**	**3,496**

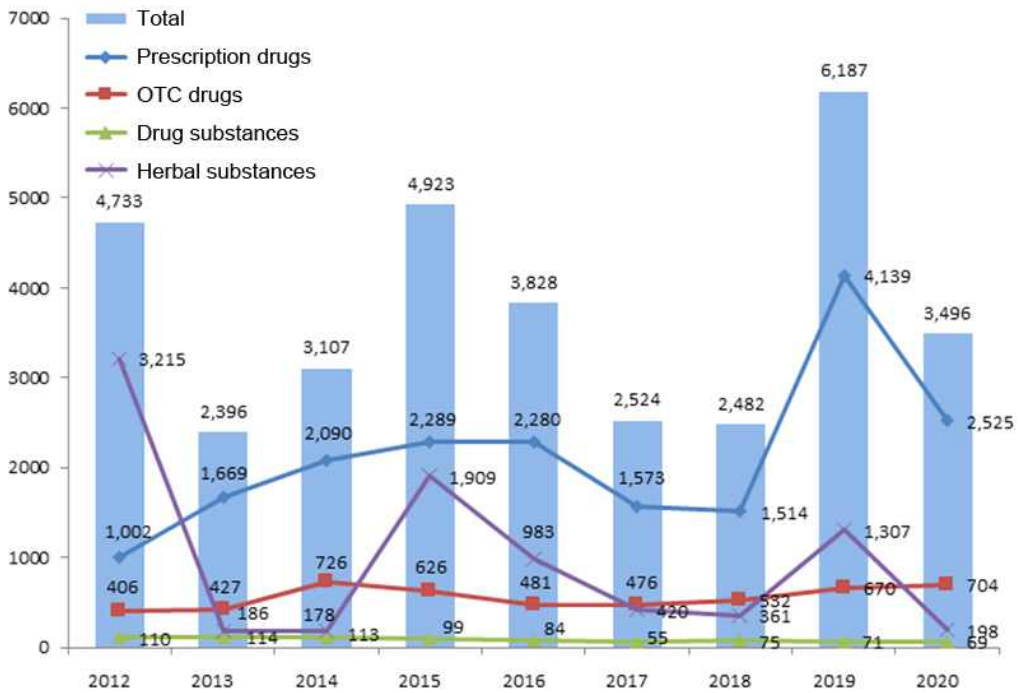

Figure 2. Approval (Notification) Status of Drugs by Drug Type (2012-2020)

1.2. Approval of New Drugs

A total of 40 new drug items were approved in 2020, including 34 chemical drugs (5 manufactured items and 29 imported items) and 6 biopharmaceuticals (6 imported items). For the number of ingredients in these new drugs, 20 new ingredients were approved including 16 ingredients from chemical drugs and 4 ingredients from biopharmaceuticals (Refer to Table 12, and refer to Table 15 for the complete list of new drugs).

It was found that imported items still comprised most of the new drugs with 87.5%.

Table 12. Approval Status of New Drugs in 2020

(Unit: number of items)

Category	Total [number of ingredients]	Chemicals	Biopharma-ceuticals	Herbal medicinal preparations
Total	40[1] (100.0%) [20 (100.0%)]	34[2] [16]	6 [4]	0 [0]
Manufactured	5 (12.5%) [2 (10.0%)]	5 [2]	0 [0]	0 [0]
Imported	35 (87.5%) [18 (90.0%)]	29 [14]	6 [4]	0 [0]

1) Out of 40 items, there were 2 items designated as both orphan drug and new drug.

2) Chemical drugs newly approved in 2020 were 33 items, and the items designated as new drugs according to the post-approval change were 7 items (Refer to Table 15).

Based on the current status of new drug approvals after 2010, the number of new drug approvals averaged 32 per year over the past 11 years. Approvals of new drugs have been slow since 2016, but more new drugs were approved than the average from 2019 to 2020 (Refer to Table 13 and Figure 3).

According to the ratio of imported items among new drugs approved in 2020, imported items and manufactured items accounted for 87.5%

and 12.5%, respectively, which shows that the introduction of imported drugs to the domestic market still influences the total number of new drugs. As for the number of ingredients, imported and manufactured items accounted for 90.0% and 10.0%, respectively, which shows that most of the new substances introduced to the domestic market in 2020 were imported items. New drugs developed in Korea have been steadily approved by 1 or 2 items each year (5 items in 2015) and a visible development outcome was seen with 5 items in 2015. However, the approval of new drugs developed in Korea faltered in 2019 and 2020 with no approved items.

Table 13-1. Approval Status of Chemical, Biopharmaceuticals and Herbal Medicinal Preparations as New Drugs by Year (2010-2020) (Including Revoked and Withdrawn Items)

(Unit: number of items)

Category		2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
No. of Approved Items[1)]		49	31	17	23	49	34	25	29	15	35	40
(Number of new drug ingredients)		(26)	(22)	(14)	(15)	(27)	(19)	(10)	(18)	(12)	(21)	(20)
Chemicals	New drugs developed in Korea	1	2	2	1	1	5	1	1	2	0	0
	Manufactured	3	8	3	3	3	6	2	1	2	4	5
	Imported	43	17	10	13	38	18	19	16	9	24	29
Biopharmaceuticals	New drugs developed in Korea	0	0	0	0	0	0	0	1	0	0	0
	Manufactured	0	0	0	0	0	0	0	1	0	0	0
	Imported	1	6	4	6	8	10	4	11	4	7	6
Herbal medicinal preparati	Manufactured	0	0	0	0	0	0	0	0	0	0	0
	Imported	2	0	0	1	0	0	0	0	0	0	0

1) The number of new drugs approved in the corresponding year including items designated as new drugs according to the post-approval change (6 chemical drugs and 1 biopharmaceutical drug)

2) In the case of new drugs developed in Korea, items with several strengths are indicated as one item.

3) The number of manufactured and marketed items includes the number of drugs developed in Korea.

Table 13-2. Approval Status of New Drugs by Year (2010-2020)

(Including Revoked and Withdrawn Items)

(Unit: number of items)

Category	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Manufactured (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%)
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%)
No. of items	49	31	17	23	49	34	25	29	15	35	40

According to an analysis of new drug approvals since 2010 by drug therapeutic class, 19 nervous system drug items in 2010, 6 urinary reproductive organ drug items (3 ingredients) in 2011, 6 anticancer drug items (four ingredients) in 2012, 6 antidiabetic drug items (3 ingredients) in 2013, 16 nervous system drug items (5 ingredients) in 2014, nervous system drugs (3 ingredients) and antidiabetic drugs (4 ingredients) in 2015, 14 anti-tumor drug items (7 ingredients) in 2016, 11 anti-tumor drug items (5 ingredients) in 2017, 4 other chemotherapy drug items in 2018 (2 ingredients), 13 anti-tumor drug items (5 ingredients) in 2019, and 13 anti-tumor drug items (6 ingredients) in 2020 took the largest proportion, respectively. In order from largest to smallest, the accumulated numbers of new drug approvals for the past 10 years were anti-tumor drugs (72 items), nervous system drugs (56 items), and antidiabetic drugs (32 items) (Refer to Table 14).

Table 14. Therapeutic Class of New Drug Approvals by Year (2010-2020)

(Including New Drugs that is Revoked, Withdrawn or with a Post-Approval Change)

(Unit: number of items)

Category	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020		Total
											Approval	Post-approval change	
Nervous system drugs	19	0	1	1	16	8	2	0	0	9	9	0	65
Antineoplastic drugs	8	3	6	4	7	5	14	11	1	13	7	6	85
Antidiabetic drugs	1	3	1	6	11	8	0	0	2	0	0	0	32
Chemo-therapeutics	7	1	1	0	2	5	2	3	4	4	5	0	34
Cardiovascular drugs	5	3	0	0	1	2	6	9	1	0	3	0	30
Respiratory organ drugs	3	1	0	0	4	1	2	1	0	1	0	0	13
Urogenital drugs	0	6	0	2	0	0	0	0	0	0	0	0	8
Drugs for sensory organs	1	1	2	0	3	0	0	0	0	3	0	0	10
Antiallergic drugs	0	1	2	3	1	0	0	8	2	1	3	0	21
Others	5	12	4	7	4	9	6	3	5	8	6	1	70
Total	**49**	**31**	**17**	**23**	**49**	**38**	**32**	**35**	**15**	**39**	**33**	**7**	368
											40		

Figure 3. Approval Status of New Drugs by Year (2010-2020) (Including New Drugs that is Revoked, Withdrawn or with a Post-Approval Change) [Refer to Table15]

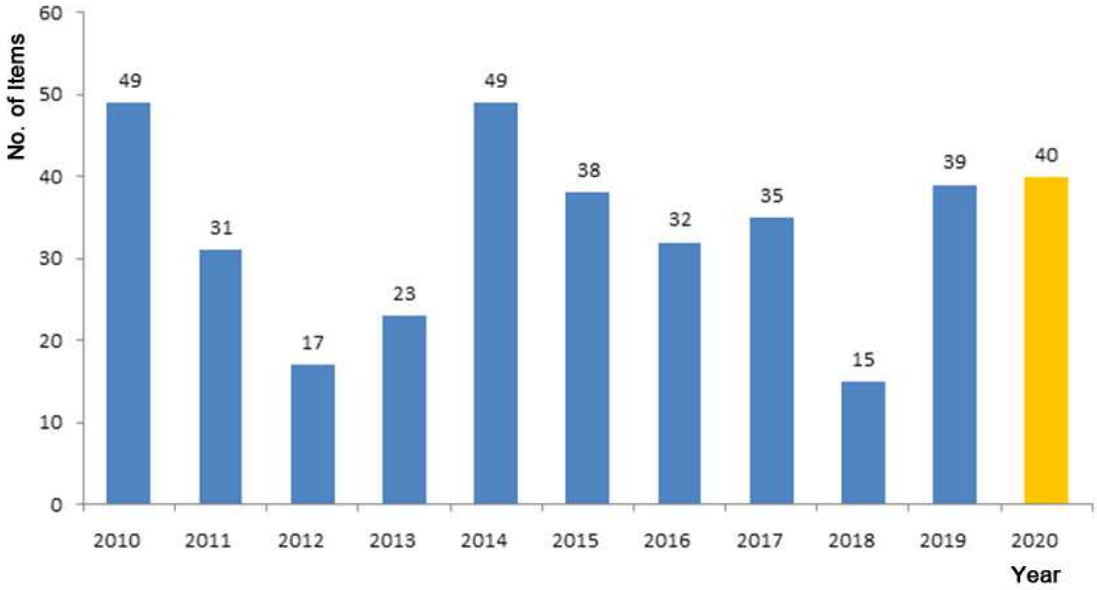

Table 15. 2020 New Drug Approval List

(Including items designated as new drugs according to the post-approval change)

□ Chemicals, ▨ Biopharmaceuticals

No.	Manufactured/ Imported	Product	Company	Date of Approval	Classification Code	Efficacy/Effectiveness (partially omitted)
1	Imported	Taleaje Tab. 10mg (Mirogablin besilate)	Daiichi Sankyo Korea Co., Ltd.	2020-01-23	[01190] Miscellaneous central nervous system drugs	Treatment of peripheral neuropathic pain
2	Imported	Taleaje Tab. 2.5mg (Mirogablin besilate)				
3	Imported	Taleaje Tab. 15mg (Mirogablin besilate)				
4	Imported	Taleaje Tab. 5mg (Mirogablin besilate)				
5	Imported	Smyraf tablet 100mg (Peficitinib hydrobromide)	Astellas Pharma Korea Inc.	2020-01-23	[01420] Non-specific immunogen preparations	Treatment of moderate or severe active rheumatoid arthritis in adults who have inadequate response to or do not tolerate one or more disease-modifying antirheumatic drugs (DMARDs).
6	Imported	Smyraf tablet 50mg (Peficitinib hydrobromide)				
7	Imported	CRESEMBA® Injection 200mg (isavuconazonium sulfate)	Pfizer Korea	2020-01-29	[06290] Miscellaneous chemo-therapeutics	1. Treatment of invasive aspergillosis in adults aged over 18 2. Treatment of invasive mucormycosis in which administration of amphotericin B is inappropriate
8	Imported	CRESEMBA® Capsules 100mg (isavuconazonium sulfate)				
9	Imported	Delstrigo tablets	MSD Korea Co., Ltd.	2020-01-29	[06290] Miscellaneous chemo-therapeutics	Treatment of HIV-1 infection in adult patients who have not received antiretroviral regimen in the past, or who demonstrated stable inhibitory effect on virus level(HIV-1 RNA < 50 copies/mL) for at least 6 months with no history of treatment failure to the current antiretroviral regimen and do not have substitutions associated with resistance to the individual components of this drug.

No.	Manufactured/ Imported	Product	Company	Date of Approval	Classification Code	Efficacy/Effectiveness (partially omitted)
10	Imported	Vizimpro® Tablets 15mg (dacomitinib monohydrate)	Pfizer Korea	2020-02-14	[04210] Antineoplastic drugs	First-line treatment of patients with local progressive or metastatic non-small cell lung cancer (NSCLC) with mutation in epithelial cell growth factor receptor (EGFR) exon 19 deletion or exon 21L858R substitution
11	Imported	Vizimpro® Tablets 45mg (dacomitinib monohydrate)				
12	Imported	Vizimpro® Tablets 30mg (dacomitinib monohydrate)				
13	Imported	Ranexa Prolonged Release Tablet 375mg (ranolazine)	Menarini Korea Ltd.	2020-03-16	[02190] Miscellaneous cardiovascular drugs	Combination therapy for symptomatic treatment of patients with stable angina that is not properly controlled with first-line angina treatment (e.g. beta-blocker and/or calcium antagonist) or who do not have tolerance
14	Imported	Ranexa Prolonged Release Tablet 500mg (ranolazine)				
15	Imported	Ranexa Prolonged Release Tablet 750mg (ranolazine)				
16	Imported	Ultomiris Inj. (ravulizumab)	Handok Inc.	2020-05-21	[06390] Miscellaneous biologics	Treatment of paroxysmal nocturnal hemoglobinuria (PNH) in adults
17	Imported	NUBEQA tablets 300mg (Darolutamide)	Bayer Korea Ltd.	2020-05-27	[04210] Antineoplastic drugs	Treatment of patients with high-risk, non-metastatic, castration-resistant prostate cancer
18	Imported	Rinvoq extended-release tablet 15mg (Upadacitinib Hemihydrate)	AbbVie Korea. LTD	2020-06-04	[01420] Non-specific immunogen preparations	Treatment of moderate to severe active rheumatoid arthritis in adults who have inadequate response to or do not tolerate one or more disease modifying antirheumatic drugs (DMARDs).
19	Imported	Beovu solution for injection (Brolucizumab)	Novartis Korea	2020-06-15	[04390] Treatment and diagnosis of other tissue cells	Treatment of neovascular (wet) age-related macular degeneration
20	Imported	Equfina Film Coated Tablets 50mg (safinamide mesilate)	Eisai Korea. Inc	2020-06-24	[01190] Miscellaneous central nervous system drugs	Adjuvant therapy of Levodopa -containing agents in patients with idiopathic Parkinson's disease with end of dose motor fluctuations

No.	Manufactured/ Imported	Product	Company	Date of Approval	Classification Code	Efficacy/Effectiveness (partially omitted)
21	Imported	Veklury Solution for IV Injection (remdesivir)	Gilead Science Korea	2020-07-24	[06290] Miscellaneous chemo-therapeutics	Patients who have been confirmed with COVID-19 by PCR tests, etc. and are hospitalized with one or more of the following serious conditions: · Patients with oxygen saturation (SpO2) in room air ≤94% · Patients who need supple-mentary oxygen treatment · Patients who require non-invasive or invasive mecha-nical ventilation or extra-corporeal membrane oxygenation (ECMO)
22	Imported	Veklury lyophilized Powder for IV injection (remdesivir)				
23	Imported	Talzenna® Capsules 1mg (talazoparib tosylate)	Pfizer Korea	2020-07-30	[04210] Antineoplastic drugs	Administer as monotherapy in adult patients with local progressive or metastatic breast cancer who have previously received chemo-therapy and have germline BRCA (gBRCA) mutation HER2-negative breast cancer
24	Imported	Talzenna® Capsules 0.25mg (talazoparib tosylate)				
25	Imported	Crysvita solution for injection 10 mg (burosumab, genetical recombination)	Kyowa Kirin Korea Co., Ltd.	2020-09-17	[03990] Miscellaneous metabolic drugs	FGF23-related hypopho-sphatemia rickets and osteomalacia
26	Imported	Crysvita solution for injection 20 mg (burosumab, genetical recombination)				
27	Imported	Crysvita solution for injection 30 mg (burosumab, genetical recombination)				
28	Manufatured	Resyno ONE Inj. (4:1 w/w mixed hydrogel of sodium hyaluronate gel crosslinked by divinyl sulfone and sodium hyaluronate fluid)	YooYoung Pharmaceuti cal Co., Ltd.	2020-10-30	[03990] Miscellaneous metabolic drugs	Osteoarthritis of knee joint

No.	Manufactured/ Imported	Product	Company	Date of Approval	Classification Code	Efficacy/Effectiveness (partially omitted)
29	Manufatured	Zebinix Tablet 400mg (eslicarbazepine acetate (micronised))	Whan In Pharm. Co., Ltd.	2020-11-10	[01130] Antiepileptics	• Monotherapy for partial seizures with or without secondary systemic seizures in adults who are newly diagnosed with epilepsy • Adjunctive therapy for partial seizures with or without secondary systemic seizures in children 6 years or older or adults
30	Manufatured	Zebinix Tablet 200mg (eslicarbazepine acetate (micronised))				
31	Manufatured	Zebinix Tablet 600mg (eslicarbazepine acetate (micronised))				
32	Manufatured	Zebinix Tablet 800mg (eslicarbazepine acetate (micronised))				
33	Imported	Erleada Tab. (apalutamide)	Janssen Korea Ltd.	2020-12-30	[04210] Antineoplastic drugs	Combined with androgen deprivation therapy (ADT) for treatment of patients with metastatic hormone-sensitive prostate cancer (mHSPC)
34	Imported	Kynteles Inj. (vedolizumab)	Takeda Pharmaceuticals Korea Co., Ltd.	Designated as a new drug (2020.1.15.) 2015-06-19	[04390] Treatment and diagnosis of other tissue cells	1. Ulcerative colitis Treatment of moderate to severe active ulcerative colitis that does not respond, becomes inactive, or does not have tolerance to universal treatment (corticosteroids or immunosuppressants) or tumor necrosis factor-α inhibitor 2. Crohn's disease Treatment of moderate to severe active Crohn's disease that does not respond, becomes inactive, or does not have tolerance to universal treatment (corticosteroids or immunosuppressants) or tumor necrosis factor-α inhibitor

No.	Manufactured/ Imported	Product	Company	Date of Approval	Classification Code	Efficacy/Effectiveness (partially omitted)
35	Imported	Venclexta tablet 100mg (Venetoclax)	AbbVie Korea Ltd.	Designated as a new drug (2020.3.26.) 2019-05-29	[04210] Antineoplastic drugs	Chronic lymphocytic leukemia Combination therapy with rituximab in adult patients with chronic lymphocytic leukemia who have previously received at least one treatment Monotherapy in adult patients with chronic lymphocytic leukemia that has relapsed due to or refractory to chemoimmunotherapy and B-cell receptor pathway inhibitors Acute myeloid leukemia Combination therapy with azacitidine or decitabine in adult patients who are newly diagnosed with acute myeloid leukemia, and who are 75 years of age or older or have a comorbidity that is not suitable for intensive induction chemotherapy
36	Imported	Venclexta tablet 10mg (Venetoclax)				
37	Imported	Venclexta tablet 50mg (Venetoclax)				
38	Imported	Alunbrig tab.30mg (brigatinib)	Takeda Pharmaceuticals Korea Co., Ltd.	Designated as a new drug (2020.8.27.) 2018-11-30	[04210] Antineoplastic drugs	Treatment of patients with anaplastic lymphoma kinase (ALK) positive progressive or metastatic non-small cell lung cancer
39	Imported	Alunbrig tab.90mg (brigatinib)				
40	Imported	Alunbrig tab.180mg (brigatinib)				

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

Table 16. List of New Drugs Developed in Korea (1999-2020) (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	Antidiabetic drug	2012.6.27
20	Duvie Tab. 0.5mg	Chong Kun Dang Pharm.	Lobeglitazone sulfate	Antidiabetic drug	2013.7.4
21	RIAVAX Inj.	GemVax & 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	Antidiabetic drug	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

※ Excluding revoked items

1.3. Approval of Orphan Drugs

In 2020, a total of 28 orphan drug items were approved (including 4 new orphan drugs), which were all imported drugs and 14 chemical drug items and 14 biopharmaceutical items were approved. Furthermore, 16 ingredients were approved, including 8 chemical drug ingredients, and 8 biopharmaceutical ingredients (Refer to Table 17).

Table 17. Approval Status of Orphan Drugs in 2020

(Unit: number of items)

Category	Total (number of ingredients)	Chemicals	Biopharma-ceuticals	Herbal medicinal preparations
Import	28 (16)	14 (8)	14 (8)	0
New orphan drugs	4 (2)	0	4 (2)	0

According to orphan drug approvals and notifications since 2010, the number of items approved was similar until 2014, but 49 items were approved in 2015, which was 1.8 times more than the annual average of approved items for the previous 5 years (27 items). This seems to be the outcome of conducting a GMP pre-audit, review of specifications and test methods, and submission of risk management plans for orphan drugs since July 2015 (Refer to Table 18 and Figure 4). The number of orphan drug approvals has been decreasing since 2017, and 11 items and 28 items were approved in 2019 and 2020, respectively.

Table 18. Approval Status of Orphan Drugs by Year (2010-2020)

(Including Revoked and Withdrawn Items)

(Unit: number of items)

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

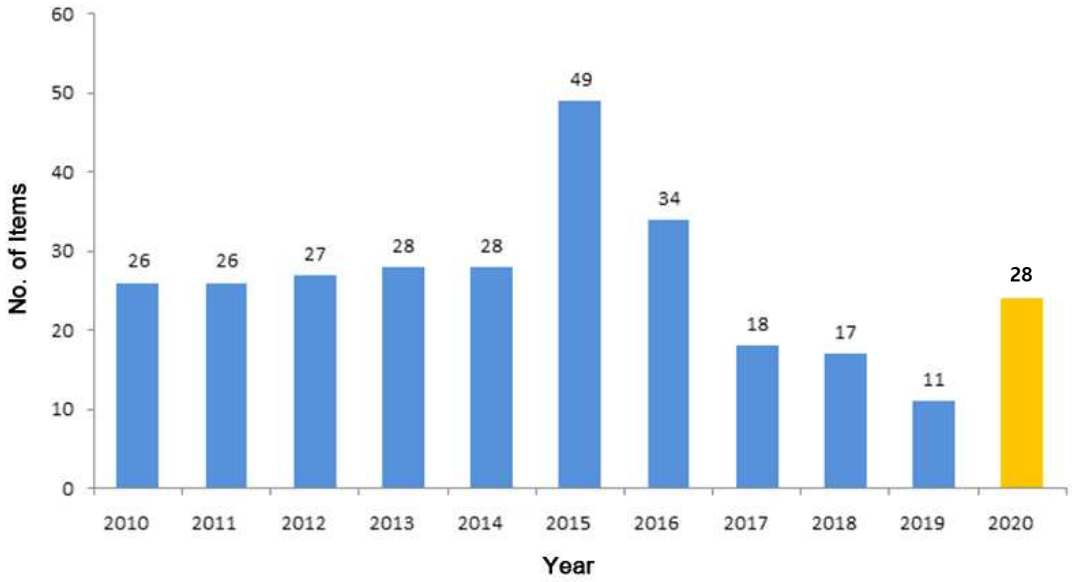

Figure 4. Approval Status of Orphan Drugs (2010-2020)

* A total of 24 items excluding new orphan drugs in 2020

In addition, a total of 19 ingredients were designated as orphan drugs in 2020 (Refer to Table 19).

Table 19. Ingredients of Newly Designated Orphan Drugs in 2020

No.	Ingredient (generic name)	Indication
1	Satralizumab (Inj.)	Neuromyelitis optica spectrum disorder
2	Tepotinib hydrochloride (oral)	Local progressive or metastatic non-small cell lung carcinoma with METex14 skipping alteration
3	Lorlatinib (oral)	Treatment of patients with anaplastic lymphoma kinase (ALK) positive non-small cell lung carcinoma who have been previously treated with ALK inhibitors - If treated with Alectinib or Ceritinib as a first-line ALK inhibitor; or - If treated with Crizotinib or at least one other ALK inhibitors
4	Mogamulizumab (Inj.)	Treatment of patients with Mycosis Fungoides or Sézary syndrome who have previously received more than one systemic therapy
5	Pexidartinib hydrochloride (oral)	Treatment of adult patients with Tenosynovial Giant Cell Tumor (TGCT) with severe morbidity or functional limitation which is accompanied with symptoms and difficult to improve by surgery
6	Epoprostenol (Inj.)	Improvement of motor performance in patients with pulmonary arterial hypertension corresponding to WHO functional classification III-IV
7	Mobocertinib (oral)	Treatment in patients with non-small cell lung carcinoma (NSCLC) with an epidermal growth factor receptor (EGFR) exon 20 insertion mutation that have been treated previously
8	Voretigene neparvovec (Inj.)	Treatment of adult and pediatric patients with inherited retinal dystrophy with biallelic RPE65 mutations
9	Zanubrutinib (oral)	Mantle cell lymphoma which received more than one treatment
10	Capmatinib (oral)	Non-small cell lung carcinoma with confirmed deletion of MET Exon 14
11	Tirabrutinib (oral)	Relapsed or refractory B-cell primary central nervous system lymphoma
12	Ciltacabtagene autoleucel (Inj.)	Treatment of relapsed or refractory multiple myeloma which received previous treatment including proteasome inhibitors, immunomodulators and anti-CD38 antibody
13	Lurbinectedin (Inj.)	Treatment of adult patients with advanced metastatic small cell lung cancer in which first-line platinum-containing chemotherapy was failed
14	Selumetinib (oral)	Treatment of children 3 years of age or older with type 1 neurofibromatosis accompanied by symptomatic and inoperable plexiform neurofibroma

No.	Ingredient (generic name)	Indication
15	Pretomanid (oral)	Combination therapy with Bedaquiline and Linezolid for extensive drug-resistant tuberculosis (XDR-TB) and treatment-intolerant/non-responsive multi-drug resistant tuberculosis (TI/NR MDR-TB) in adults
16	Ropeginterferon alfa-2b (Inj.)	Treatment of patients with polycythemia vera in low-risk groups (but limited to patients requiring cell reduction therapy) and high-risk groups
17	Pegaspargase (Inj.)	Combination therapy with other anti-tumor drugs in treatment of acute lymphocytic leukemia
18	Encorafenib (oral)	Combination therapy with Cetuximab in treatment of adult patients with metastatic colorectal cancer with previous treatment history and identified BRAF V600E mutation
19	Selinexor (oral)	1. Combination therapy with Dexamethasone for adult patients with relapsed or refractory multiple myeloma, in which the patient previously received at least two protease inhibitors, at least two immunomodulatory amide treatments and at least one CD38 antibody treatment among the four treatment regimens. 2. Treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma after two or more systemic treatments

1.4. Approval and Notification Status by Major Therapeutic Class and Classification Code

Drug products approved and notified in 2020 by drug therapeutic class, in descending order, are as follows: circulatory system drugs such as hypertension drugs (18.7%), nervous system drugs such as dementia drugs (17.8%), digestive system drugs such as stomach ulcer drugs (13.7%), metabolic drugs such as antidiabetic drugs (12.1%), and antibiotic preparations (5.6%) (Refer to Table 20 and Figure 5).

Table 20. Number of Approved and Notified Items by Therapeutic Class in 2020 (Including Revoked and Withdrawn Items)

(Unit: number of items)

<table>
<tr><th rowspan="2">Classification Code / Total</th><th rowspan="2">Nervous system drugs</th><th rowspan="2">Cardio-vascular drugs</th><th rowspan="2">Digestive system drugs</th><th colspan="2">Metabolism</th><th rowspan="2">Antibiotics</th><th rowspan="2">Chemo-therapy</th><th rowspan="2">Blood and body fluid drugs</th><th rowspan="2">Antiallergic drugs</th><th rowspan="2">Others</th></tr>
<tr><th>Others</th><th>Antidiabe-tic drugs</th></tr>
<tr><td rowspan="2">3,110</td><td rowspan="2">554
(17.8%)</td><td rowspan="2">581
(18.7%)</td><td rowspan="2">425
(13.7%)</td><td>156
(5.0%)</td><td>221
(7.1%)</td><td rowspan="2">95
(3.1%)</td><td rowspan="2">75
(2.4%)</td><td rowspan="2">121
(3.9%)</td><td rowspan="2">102
(3.3%)</td><td rowspan="2">780
(25.1.%)</td></tr>
<tr><td colspan="2">377
(12.1%)</td></tr>
</table>

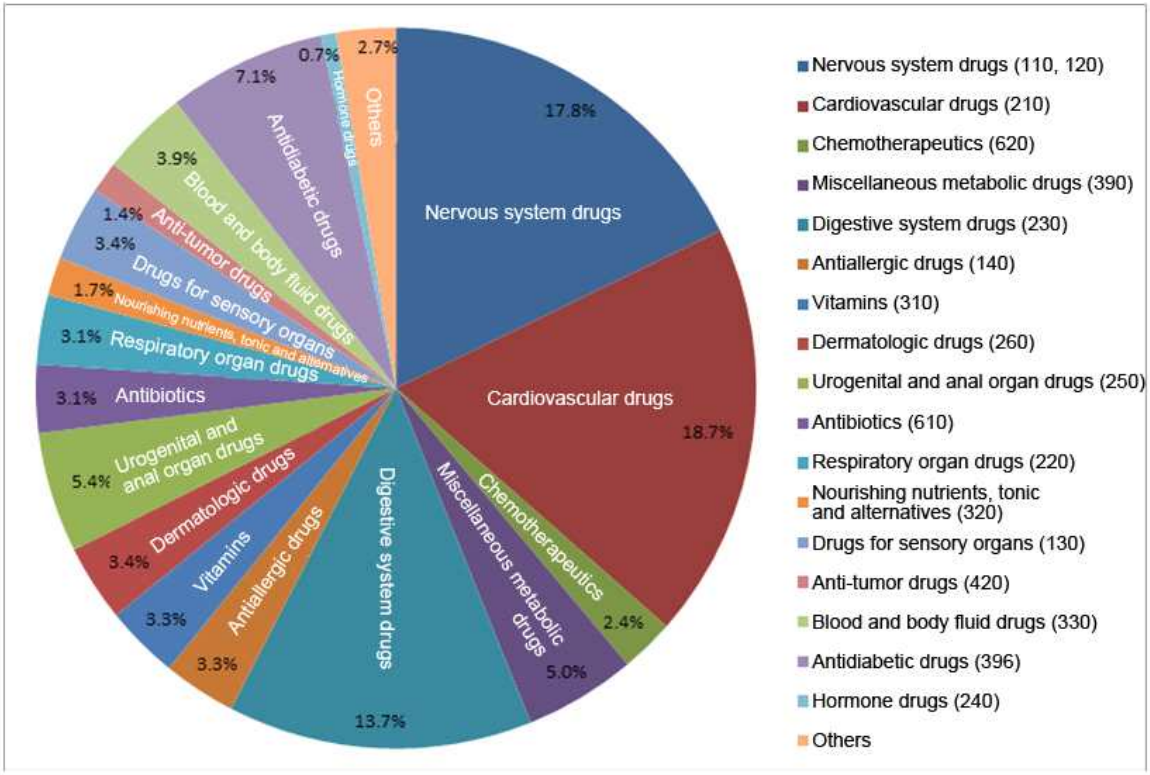

Figure 5. Ratio of Approval (Notification) Cases Classified by Major Therapeutic Class in 2020

As for approvals and notifications by therapeutic class since 2011, nervous system drugs, circulatory system drugs, digestive system drugs and metabolic drugs have made up a large part, as in the previous year. The highest percentage of approved/notified drugs in 2020 was circulatory system drugs, which was the same as in 2019. Most (97.4%) of the circulatory system drugs were antihypertensives, hyperlipidemia drugs, and miscellaneous cardiovascular drugs. The drugs that made up the second largest share were nervous system drugs, most of which (64.6%) were antipyretics, analgesics, anti-inflammatory drugs and miscellaneous central nervous system agents (Refer to Figure 6 and Table 22).

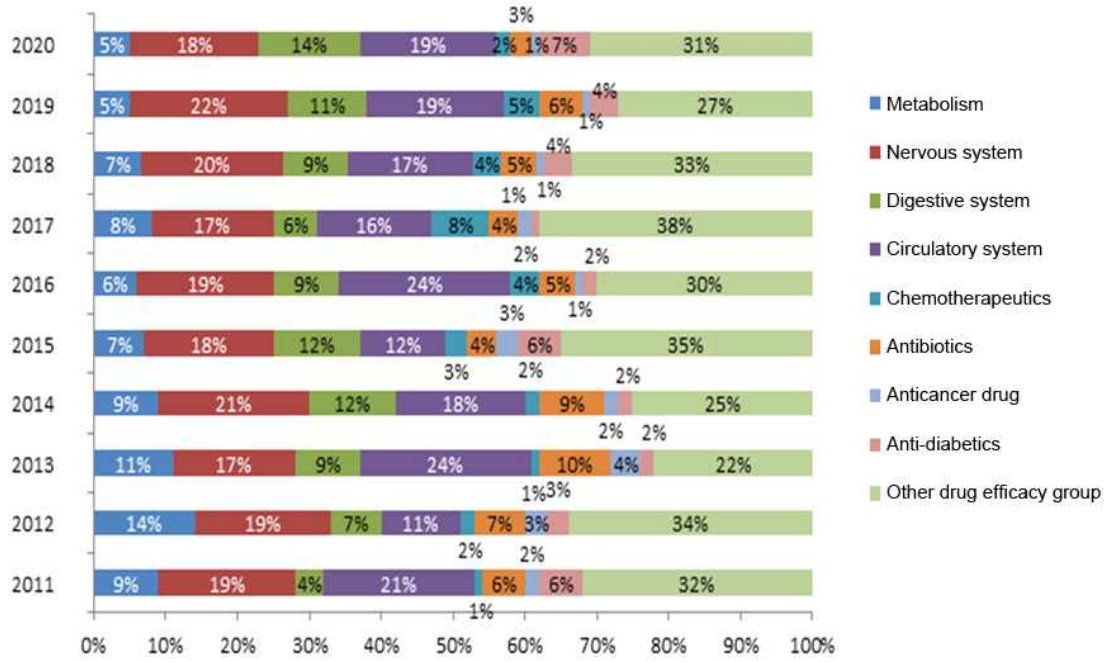

Figure 6. Ratio of Approval (Notification) Cases of Drugs by Drug Therapeutic Class by Year (2011-2020)

According to the detailed information on approval and notification status by unique classification code for sub-therapeutic class, antipyretic, analgesic, and anti-inflammatory drugs (code 114) comprised 7.3% (227 items) each, remaining in the top 5 for the recent 5 years. Also, miscellaneous circulatory system drugs (7.7%, 240 items), peptic ulcer drugs (7.3%, 227 items), and antidiabetic drugs (7.1%, 221 items) ranked high (Refer to Table 21).

Table 21. Unique Classification Code of Top 5 Approved Items (2016-2020)

(Including Revoked and Withdrawn Items)

	2016		2017		2018		2019		2020	
	Efficacy classification (classification code)	No. of items	Efficacy classification (classification code)	No. of items	Efficacy classification (classification code)	No. of items	Efficacy classification (classification code)	No. of items	Efficacy classification (classification code)	No. of items
1	Antihypertensives (214)	366 (13.3%)	Miscellaneous chemotherapeutics (629)	166 (8.1%)	Antipyretics, analgesics, and anti-inflammatory drugs (114)	152 (7.4%)	Antihypertensives (214)	482 (10.0%)	Miscellaneous cardiovascular drugs (240)	240 (7.7%)
2	Drugs for atherosclerosis (218)	227 (8.2%)	Antipyretics, analgesics, and anti-inflammatory drugs (114)	146 (7.1%)	Antihypertensives (214)	145 (7.1%)	Miscellaneous central nervous system drugs (119)	374 (7.8%)	Peptic ulcer drugs (232)	227 (7.3%)

3	Miscellaneous central nervous system drugs (119)	177 (6.4%)	Antihypertensives (214)	138 (6.7%)	Miscellaneous central nervous system drugs (119)	128 (6.3%)	Antipyretics, analgesics, and anti-inflammatory drugs (114)	351 (7.3%)	Antidiabetic drugs (396)	221 (7.1)
4	Antipyretics, analgesics, and anti-inflammatory drugs (114)	173 (6.3%)	Miscellaneous central nervous system drugs (119)	112 (5.5%)	Drugs for atherosclerosis (218)	117 (5.7%)	Peptic ulcer drugs (232)	340 (7.1%)	Antipyretics, analgesics, and anti-inflammatory drugs (114)	190 (6.1%)
5	Peptic ulcer drugs (232)	153 (5.5%)	Miscellaneous metabolic drugs (399)	112 (5.5%)	Miscellaneous metabolic drugs (399)	102 (5.0%)	Drugs for atherosclerosis (218)	261 (5.4%)	Drugs for atherosclerosis (218)	175 (6.0%)
	No. of drug products approved and notified in 2016	2,761 (100%)	No. of drug products approved and notified in 2017	2,049 (100%)	No. of drug products approved and notified in 2018	2,046 (100%)	No. of drug products approved and notified in 2019	4,809 (100%)	No. of drug products approved and notified in 2020	3,110 (100%)

Table 22. Approval and Notification Status of Drug Products by Major Therapeutic Class in 2020

Classification	Classification Code		No. of items
Nervous system drugs	111	General anesthetics	1
	112	Hypnotic sedatives	23
	113	Antiepileptics	45
	114	Antipyretics, analgesics, and anti-inflammatory drugs	190
	116	Antivertigo drugs	0
	117	Psychotropics	96
	119	Miscellaneous central nervous system drugs	168
	121	Local anesthetics	6
	122	Skeletal muscle relaxants	14
	123	Autonomic nervous system drugs	7
	124	Antispasmodics	4
	Subtotal		554
Ophthalmology and ENT	131	Ophthalmic drugs	91
	132	Otic and nasal drugs	14
	Subtotal		105
Cardiovascular drugs, and blood and body fluid drugs	212	Antiarrhythmic drugs	0
	214	Antihypertensives	139
	215	Capillary stabilizers	15
	217	Vasodilators	0
	218	Drugs for atherosclerosis	187
	219	Miscellaneous cardiovascular drugs	240
	332	Hemostatics	3
	333	Anticoagulants	66
	339	Miscellaneous blood and body fluid drugs	52
	Subtotal		702
Respiratory organs and antiallergic drugs	141	Antihistamines	30
	142	Non-specific immunogen preparations	39
	149	Miscellaneous antiallergic drugs	33
	222	Antitussive expectorants	67
	223	Inhalation treatment preparations	5
	229	Miscellaneous respiratory organ drugs	25
	Subtotal		199

Classification	Classification Code		No. of items
Digestive system drugs	231	Dental and oral drugs	30
	232	Peptic ulcer drugs	227
	233	Stomachics and digestives	9
	234	Antacids	20
	235	Emetics and antiemetics	14
	237	Intestinal drugs	13
	238	Purgatives and clysters	32
	239	Miscellaneous digestive system drugs	80
	Subtotal		425
Urinary and reproductive system drug	253	Emmenagogues	0
	254	Contraceptives	5
	256	Hemorrhoidal preparations	4
	259	Miscellaneous urogenital and anal organ drugs	159
	Subtotal		168
Metabolic drugs	311	Vitamin A and D preparations	21
	313	Vitamin B preparations (excluding vitamin B1)	2
	315	Vitamin E and K preparations	1
	316	Multivitamin preparations (excluding multivitamin complex with A and D)	11
	319	Miscellaneous vitamin preparations	68
	321	Calcium preparations	15
	322	Mineral preparations	15
	325	Protein and amino acid preparations	9
	329	Miscellaneous nourishing nutrients, tonic and alternatives	14
	391	Liver disease drugs	16
	392	Antidotes	6
	394	Gout preparations	7
	395	Enzyme preparations	19
	399	Miscellaneous metabolic drugs	108
	Subtotal		312
Antidiabetic drugs	396	Antidiabetic drugs	221
	Subtotal		221
Anticancer drugs	421	Antineoplastic drugs	29
	429	Miscellaneous anti-tumor drugs	15
	Subtotal		44

Classification	Classification Code		No. of items
Antibiotics	611	Acting mainly on gram-positive bacteria	8
	612	Acting mainly on gram-negative bacteria	1
	614	Acting mainly on gram-positive bacteria, rickettsia, and virus	7
	615	Acting mainly on gram- positive/negative bacteria, rickettsia, and virus	0
	618	Acting mainly on gram- positive/negative bacteria	63
	619	Miscellaneous antibiotic drugs (including complex antibiotic drugs)	16
	Subtotal		95
Chemo-therapeutics	629	Miscellaneous chemotherapeutics	75
	Subtotal		75
Others (classification that does not belong to the above therapeutic class)			210
Total			3110

2

Approval status of Drugs (Chemical Drugs)

2. Approval Status of Drugs (Chemical Drugs)

The number of chemical drugs approved in 2020 by review type is as follows: new drugs (28), orphan drugs (14), drugs requiring data submissions (332 including 6 incrementally modified drugs), and active pharmaceutical ingredients (18) items. The highest proportion of drugs requiring data submission (326 items) was drugs with new compositions accounting for 55.8% (182 items), followed by drugs with new salts (22.7%, 74 items) and drugs with a new dosage form (same route of administration) (12.0%, 39 items) (Refer to Table 23).

Table 23. Approval Status of Pharmaceutical Drugs (Chemical Drugs) by Review Type in 2020

<table>
<tr><th>Type</th><th colspan="4">Review Type</th><th colspan="2">No. of Approved Items</th></tr>
<tr><td>1</td><td rowspan="2">New drugs (28)</td><td colspan="3">New drugs</td><td colspan="2">28</td></tr>
<tr><td>2</td><td colspan="2">New orphan drugs</td><td rowspan="2">Orphan drugs (14)</td><td colspan="2">0</td></tr>
<tr><td>3</td><td colspan="3">Orphan drugs</td><td colspan="2">14</td></tr>
<tr><td>4</td><td colspan="4">Drugs requiring data submission</td><td colspan="2">332</td></tr>
<tr><td rowspan="2">4-1</td><td rowspan="2" colspan="2">Incrementally modified drugs</td><td>New composition</td><td rowspan="2">6</td><td>2</td></tr>
<tr><td>New dosage form</td><td>4</td></tr>
<tr><td>4-2</td><td rowspan="8" colspan="2">Drugs requiring data submission</td><td>New salts or isomers</td><td rowspan="8">326</td><td>74</td></tr>
<tr><td>4-3</td><td>New drug efficacy group</td><td>2</td></tr>
<tr><td>4-4</td><td rowspan="2">New composition</td><td rowspan="2">182</td></tr>
<tr><td>4-5</td></tr>
<tr><td>4-6</td><td>Change in strength</td><td>26</td></tr>
<tr><td>4-7</td><td>New mode of administration/dosage</td><td>3</td></tr>
<tr><td>4-8</td><td rowspan="2">New dosage form (same route of administration)</td><td rowspan="2">39</td></tr>
<tr><td>5</td><td colspan="4">Active pharmaceutical ingredients</td><td colspan="2">18</td></tr>
</table>

In 2020, 28 new drugs were approved (excluding new drugs to which post-approval change was made including those removed from the orphan drug list), which was the same as in 2019, and of which 23 drugs (82.1%) were imported items. The number of incrementally modified drugs decreased to 6 items in 2020 compared to 13 items in 2019 (new dosage form with the same administration route). In detail, the following drugs were approved as incrementally modified drugs: drugs of which improved usability was proven by a new dosage form (4 items), drugs of which improved usability was recognized by changes in composition (1 item), and drugs with a new composition of which improved efficacy was proven (Refer to Table 28).

In addition, since July 2018, the MFDS has been operating “pharm. together,” a government-private sector communication channel to derive improvement measures by discussing current problems or issues arising from the drug approval and review process, as well as making efforts to resolve difficulties related to the process through active and frequent communications with the industry. In 2020, a cooperative review process between the approval and review departments was established to add an indication for two or more drugs with the same clinical data (combination therapy of chemicals and biopharmaceuticals).

In November 2020, an "official communication channel" was introduced and piloted to strengthen the responsibility of counseling by officially reflecting the results of civil service counseling in approvals/ reviews during the new drug approval process. In the development stage, the existing "preliminary review system" is used and a

"pre-meeting" is established and operated in addition to the “face-to-face meeting.” In the approval/review stage, a "face-to-face review system" was introduced to operate an "initiation meeting," "complementary meeting" and "additional complementary meeting." Guidelines for the operation of the official communication channel for medical products can be found on the official MFDS website (www.mfds.go.kr) ▶ Regulation/Resources ▶ Regulatory Information ▶ Guidelines for Public Officials/Guide for Civil Petitioners. Q&A and user manuals can be found on the MFDS's official website (www.mfds.go.kr) ▶ Regulation/Resources ▶ PR Materials ▶ General PR Materials.

Meanwhile, since August 2020, MFDS has been providing a "generic drug bundle information" service so that doctors, pharmacists, and consumers can check generic drugs with the same active ingredient manufactured by the same manufacturer. This information allows you to search the active ingredient name in the generic drug bundle information section on the first page of MFDS Drug Safety World (nedrug.mfds.go.kr) to find a list of products that contain the same active ingredient as the manufacturer.

2.1. Approval Status of New Drugs

In 2020, 34 new drugs were approved (5 manufactured items and 29 import items), an increase of 6% compared to 2019. The top classification codes of the approved items are in the order of anticancer drugs (12 items), central nervous system drugs (7 items), miscellaneous chemotherapeutics (4 items), and digestive system drugs (4 items) (Refer to Table 24 to Table 26).

Table 24. Approval Status of Manufactured/Imported New Drugs (2014-2020) (Chemical Drugs)

(Unit: number of items)

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

1) Including 1 new drug with a post-approval change including removal from the orphan drug list in 2014: (removed from the orphan drug list) Symbenda Inj.

2) Including 4 new drugs with a post-approval change including removal from the orphan drug list in 2015:

(Removed from the orphan drug list) Xtandi Soft Capsule 40 mg, Volibris Tablet 5 mg, 10 mg and Zytiga Tablet 250 mg

3) Including 4 drugs designated as both new drug and orphan drug, and 3 new drugs with a post-approval change including removal from the orphan drug list in 2016:

(new orphan drug) Tecfidera Cap. 120, 240 mg, Ofev Soft Cap. 100, 150 mg

(removed from the orphan drug list) Jakavi Tab. 5, 15, 20 mg

4) Including 4 new drugs with a post-approval change including removal from the orphan drug list in 2017: (removed from the orphan drug list) Pomalyst Cap. 1, 2, 3, 4 mg

5) Including 3 items which were approved as both new drug and orphan drug in 2018:

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

6) Including 1 drug designated as both new drug and orphan drug, and 3 new drugs with a post-approval change including removal from the orphan drug list in 2019:

(new orphan drug) Cerdelga Cap. 84 mg

(Removed from the orphan drug list) Cabometyx Tab. 20, 40, 60 mg

7) Including 6 new drugs with a post-approval change including removal from the orphan drug list in 2020:

(Removed from the orphan drug list) Venclexta Tab. 10, 50, 100 mg and Alunbrig Tab. 30, 90, 180 mg

Table 25. Approval Status of New Drugs by Drug Classification Code (2014-2020) (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 organs	Drugs for parasitic 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

In 2020, 4 antiepileptic drug items, 5 miscellaneous central nervous system drug items (Parkinson's syndrome adjuvant treatment), 3 non-specific immunogen preparation items, 3 miscellaneous circulatory system drug items, 1 miscellaneous metabolic drug item, 5 miscellaneous chemotherapeutic items, and 13 antineoplastic agent items were approved.

The product names, manufacturers, dates of approval, active ingredients, efficacy and effectiveness, and mechanism of action for new drugs approved in 2020 in the sequential order of approval dates are as follows:

“Taleaje Tab. (mirogabalin besilate)” (Daiichi Sankyo Korea Co., Ltd., approved on 2020.1.23) is used for the treatment of peripheral neuropathic pain. The active ingredient “**mirogabalin besilate**” exhibits an improvement effect of neuropathic pain through selective binding to the α2-δ subunit of the voltage-gated Ca2+ channel in the central nervous system.

“Smyraf Tab. (peficitinib hydrobromide)” (Astellas Pharma Korea Inc., approved on 2020.01.23) is used for the treatment of moderate to severe active rheumatoid arthritis (including prevention of joint structure damage) in adults who have inadequate response to or do not tolerate one or more disease-modifying antirheumatic drugs (DMARDs). The active ingredient of this drug is **“peficitinib hydrobromide”**, a Janus kinase inhibitor, and exhibits an effect on rheumatoid arthritis by effectively hindering the activities of JAK1, JAK2, JAK3 and TKY2.

“CRESEMBA® Injection, CRESEMBA® Capsules (isavuconazonium sulfate)” (Pfizer Korea Ltd., approved on 2020.01.29) is used for the treatment of invasive aspergillosis and invasive mucormycosis in which administration of amphotericin B is inappropriate. The active ingredient **“isavuconazonium sulfate”** is a precursor of isavuconazole, which acts by inhibiting the cytochrome P-450-dependent enzyme, lanosterol14-alpha-demethylase.

“Delstrigo Tab.” (Organon Korea Co., Ltd., approved on 2020.01.29) is used for the treatment of HIV-1 infection in adult patients who have not previously received an antiretroviral therapy, or who demonstrated a stable inhibitory effect on the virus level for at least 6 months with no history of treatment failure with the existing antiretroviral therapy and do not have substitutions associated with resistance to the individual ingredients of this drug. The active ingredient **“doravirine”** is a pyridinone nonnucleoside reverse transcriptase inhibitor for HIV-1, **“lamivudine”** is a synthetic nucleoside analogue, and **“tenofovir**

disoproxil fumarate” is an acyclic nucleoside phosphonate diester analogue of adenosine monophosphate.

"Vizimpro® Tablets (dacomitinib monohydrate)" (Pfizer Korea Ltd., approved on 2020.02.14.) is a first-line treatment for patients with local progressive or metastatic non-small cell lung carcinoma (NSCLC) with epithelial cell growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutation. The active ingredient **“dacomitinib monohydrate”** is a selective adenosine triphosphate (ATP) competitive, irreversible small molecule inhibitor of human epithelial cell growth factor receptor (HER)/erythroblastosis oncogene B homolog (ERB) receptor tyrosine kinase (RTK), and exhibits activity in epithelial cell growth factor receptors (EGFR, HER1, ERBB1), HER2 receptor (ERBB2), HER4 receptor (ERBB4) and EGFR mutations (e.g., exon 19 deletion or exon 21 L858R substitution mutation).

“Ranexa Prolonged Release Tablet (ranolazine)” (Menarini Korea Ltd., approved on 2020.3.16) is used for the combination therapy for symptomatic treatment of patients with stable angina that is not adequately controlled with first-line antianginal treatments (e.g., beta-blocker and/or calcium antagonist) or does not have tolerance. The active ingredient **“ranolazine”** reduces intracellular sodium accumulation by inhibiting late sodium influx (late INa) from cardiac cells, resulting in reduced intracellular Ca2+ overload. By reducing these intracellular ionic imbalances during the ischemic period, antianginal and anti-ischemic effects are shown.

“Venclexta Tab. (venetoclax)” (AbbVie Korea Ltd., approved as a new drug with a post-approval change on 2020.03.26) is used as monotherapy in patients with relapsed or refractory chronic lymphocytic leukemia for chemoimmunotherapy and B cell receptor pathway inhibitors, and the active ingredient **“venetoclax”** is a selective “Bcl-2 inhibitor.”

“Nubeqa Tab. 300 mg (darolutamide)” (Bayer Korea, approved on 2020.05.27) is a drug for prostate cancer that is used for the treatment of patients with high-risk, non-metastatic, castration-resistant prostate cancer. The active ingredient **“darolutamide”** is a nonsteroid androgen receptor antagonist that acts on androgen receptors, reducing the tumor volume of prostate cancer.

“Rinvoq Extended-Release Tab. 15 mg (upadacitinib hemihydrate)” (AbbVie Korea Ltd., approved on 2020.06.04) is used for the treatment of moderate to severe active rheumatoid arthritis in adults who have inadequate response or do not have tolerance to one or more disease-modifying antirheumatic drugs (DMARDs). This drug can be administered alone or in combination with methotrexate or other non-biological DMARDs, but not with biological DMARDs or other Janus kinase (JAK) inhibitors.

The active ingredient **“upadacitinib hemihydrate”** is a selective and reversible inhibitor of selective Janus kinase (JAK) 1, indicating its effect on immune-mediated inflammatory responses.

“Equfina Film Coated Tablets 50 mg (safinamide mesilate)” (Eisai

Korea Inc., approved as a new drug with a post-approval change on 2020.06.24) is used as an adjuvant therapy for levodopa-containing agents in patients with idiopathic Parkinson's disease with symptoms of motor fluctuation. The active ingredient of this drug, **“safinamide mesilate,”** facilitates nerve transmission through activation of the neurotransmitter dopamine by inhibiting selective and reversible MonoAmine Oxidase B (MAO-B).

“Veklury Solution for IV Injection, Veklury lyophilized Powder for IV injection (remdesivir)” (Gilead Science Korea Ltd., approved on 2020.07.24) has been developed as a treatment for severe hospitalized patients among confirmed cases of coronavirus infectious disease-19.

The active ingredient **“remdesivir”** inhibits RNA-dependent RNA polymerase in the COVID-19 virus.

“Talzenna® Capsules (talazoparib tosylate)” (Pfizer Korea Ltd., approved on 2020.07.30) has the active substance **“talazoparib tosylate,”** and is used as monotherapy for the treatment of germline BRCA (gBRCA) mutation HER2-negative local progressive or metastatic breast cancer adult patients who have previously experienced chemotherapy. This is a PARP-inhibiting drug that further deletes DNA repair capabilities, leading to apoptosis as a result of irreversible DNA damage, and thereby exhibits anticancer effect.

“Alunbrig Tab. (brigatinib)” (Takeda Pharmaceuticals Co., Ltd., approved as a new drug with a post-approval change on 2020.08.27) is an anticancer drug that is used for the treatment of patients with

anaplastic lymphoma kinase (ALK) positive progressive or metastatic non-small cell lung carcinoma. The active ingredient "**brigatinib**" acts as a selective inhibitor of ALK, which can overcome resistance-related mechanisms for crizotinib, including point mutations in the ALK kinase site.

"**Resyno ONE Inj. (4:1 w/w mixed hydrogel of sodium hyaluronate gel crosslinked by divinyl sulfone and sodium hyaluronate fluid)**" (YooYoung Pharmaceutical Co., Ltd., approved on 2020.10.30) is used for osteoarthritis of the knee joint. The active ingredient "**4:1 w/w mixed hydrogel of sodium hyaluronate gel crosslinked by divinyl sulfone and sodium hyaluronate fluid**" inhibits physical damage with the viscoelasticity of hyaluronic acid, and contributes to anti-inflammatory effects by inhibiting IL-1β and TNF-α.

"**Zebinix Tablet (eslicarbazepine acetate (micronised))**" (Whan In Pharm Co., Ltd., approved on 2020.11.10.) is an anti-malignancy drug used in progressive or metastatic breast cancer patients who are positive for hormone receptor (HR) and negative for human epithelial cell growth factor2 (HER2). The active ingredient "**eslicarbazepine acetate (micronised))**" is a voltage-gated Na+ channel blocker that is metabolized as a cyclin-dependent kinase (CDK) and converted to eslicarbazepine, which has a pharmacological effect.

"**Erleada Tab. (apalutamide)**" (Janssen Korea Ltd., approved on 2020.12.30) is an anticancer drug used for the treatment of patients with metastatic hormone-sensitive prostate cancer (mHSPC). The active ingredient "**apalutamide**" is a selective androgen receptor inhibitor that

binds directly to the ligand-binding domain of androgen receptors. It leads to anti-tumor activities by reducing tumor cell proliferation and increasing cell death by interfering with androgen receptor-mediated transcription and inactivating androgen receptor agonists.

Table 26. Approval Status of New Drugs in 2020 (Chemical Drugs)

No	Manufactured / Imported	Product	Company	Date of Approval	Classification Code	Efficacy/Effectiveness (partially omitted)
1	Imported	Taleaje Tab. 10mg (Mirogablin besilate)	Daiichi Sankyo Korea Co., Ltd.	2020-01-23	[01190] Miscellaneous central nervous system drugs	Treatment of peripheral neuropathic pain
2	Imported	Taleaje Tab. 2.5mg (Mirogablin besilate)				
3	Imported	Taleaje Tab. 15mg (Mirogablin besilate)				
4	Imported	Taleaje Tab. 5mg (Mirogablin besilate)				
5	Imported	Smyraf tablet 100mg (Peficitinib hydrobromide)	Astellas Pharma Korea, Inc.	2020-01-23	[01420] Non-specific immunogen preparations	Treatment of moderate or severe active rheumatoid arthritis (including prevention of joint structure damage) in adults who have inadequate response to or do not tolerate one or more disease-modifying antirheumatic drugs (DMARDs).
6	Imported	Smyraf tablet 50mg (Peficitinib hydrobromide)				
7	Imported	CRESEMBA® Injection 200mg (isavuconazonium sulfate)	Pfizer Korea	2020-01-29	[06290] Miscellaneous chemo-therapeutics	Treatment of invasive aspergillosis and invasive mucormycosis
8	Imported	CRESEMBA® Capsules 100mg (isavuconazonium sulfate)				
9	Imported	Delstrigo tablets	MSD Korea Co., Ltd.	2020-01-29	[06290] Miscellaneous chemo-therapeutics	Treatment of HIV-1 infection in adult patients who have not previously received an antiretroviral therapy, or who demonstrated a stable inhibitory effect on the virus level (HIV-1

						RNA < 50 copies/mL) for at least 6 months with no history of treatment failure to the existing antiretroviral therapy and do not have substitutions associated with resistance to the individual ingredients of this drug.
10	Imported	Vizimpro® Tablets 15mg (dacomitinib monohydrate)	Pfizer Korea	2020-02-14	[04210] Antineoplastic drugs	Administer as a first-line treatment in patients with local progressive or metastatic non-small cell lung carcinoma (NSCLC) with epithelial cell growth factor receptor (EGFR) exon 19 deletion or exon 21L858R substitution mutation
11	Imported	Vizimpro® Tablets 45mg (dacomitinib monohydrate)				
12	Imported	Vizimpro® Tablets 30mg (dacomitinib monohydrate)				
13	Imported	Ranexa Prolonged Release Tablet 375mg (ranolazine)	Menarini Korea Ltd.	2020-03-16	[02190] Miscellaneous cardiovascular drugs	Combination therapy for symptomatic treatment of patients with stable angina that is not adequately controlled with first-line antianginal drugs (e.g. beta-blocker and/or calcium antagonist) or does not have tolerance
14	Imported	Ranexa Prolonged Release Tablet 500mg (ranolazine)				
15	Imported	Ranexa Prolonged Release Tablet 750mg (ranolazine)				
16	Imported	NUBEQA tablets 300mg (Darolutamide)	Bayer Korea Ltd.	2020-05-27	[04210] Antineoplastic drugs	Treatment of patients with high-risk, non-metastatic, castration-resistant prostate cancer
17	Imported	Rinvoq extended-release tablet 15mg (Upadacitinib Hemihydrate)	AbbVie Korea Ltd.	2020-06-04	[01420] Non-specific immunogen preparations	Treatment of moderate to severe active rheumatoid arthritis in adults who have inadequate response or do not have tolerance to one or more disease modifying antirheumatic drugs (DMARDs).
18	Imported	Equfina Film Coated Tablets 50mg (safinamide mesilate)	Eisai Korea Inc.	2020-06-24	[01190] Miscellaneous central nervous system drugs	Adjuvant therapy of Levodopa-containing agents in patients with idiopathic Parkinson's disease with end of dose motor fluctuations
19	Imported	Veklury Solution for IV Injection (remdesivir)	Gilead Science Korea	2020-07-24	[06290] Miscellaneous	Patients who have been confirmed with COVID-19

						by PCR tests, etc. and are hospitalized with one or more of the following serious conditions: ・Patients with oxygen saturation (SpO2) in room air ≤94% ・Patients who need supplementary oxygen treatment ・Patients who require non-invasive or invasive mechanical ventilation or extracorporeal membrane oxygenation (ECMO)
20	Imported	Veklury lyophilized Powder for IV injection (remdesivir)			chemo-therapeutics	
21	Imported	Talzenna® Capsules 1mg (talazoparib tosylate)	Pfizer Korea	2020-07-30	[04210] Antineoplastic drugs	Administer as monotherapy in adult patients with local progressive or metastatic breast cancer who have previously received chemo-therapy and have germline BRCA (gBRCA) mutation HER2-negative breast cancer.
22	Imported	Talzenna® Capsules 0.25mg (talazoparib tosylate)				
23	Manufactured	Resyno ONE Inj. (4:1 w/w mixed hydrogel of sodium hyaluronate gel crosslinked by divinyl sulfone and sodium hyaluronate fluid)	YooYoung Pharmaceutical Co., Ltd.	2020-10-30	[03990] Miscellaneous metabolic drugs	Osteoarthritis of knee joint
24	Manufactured	Zebinix Tablet 400mg (eslicarbazepine acetate (micronised))	Whan In Pharm. Co., Ltd.	2020-11-10	[01130] Antiepileptics	Monotherapy for partial seizures with or without secondary systemic seizures in adults who are newly diagnosed with epilepsy Adjunctive therapy for partial seizures with or without secondary systemic seizures in children 6 years or older or adults
25	Manufactured	Zebinix Tablet 200mg (eslicarbazepine acetate (micronised))				
26	Manufactured	Zebinix Tablet 600mg (eslicarbazepine acetate (micronised))				
27	Manufactured	Zebinix Tablet 800mg (eslicarbazepine acetate (micronised))				
28	Imported	Erleada Tab. (apalutamide)	Janssen Korea Ltd.	2020-12-30	[04210] Antineoplastic	Combined with androgen deprivation therapy (ADT)

					drugs	for treatment of patients with metastatic hormone-sensitive prostate cancer (mHSPC)
29	Imported	Venclexta tablet 10mg (Venetoclax)	AbbVie Korea Ltd.	2020-03-26 (Orphan, switched to new drug) * First approval :2019-05-29	[04210] Antineoplastic drugs	Chronic lymphocytic leukemia Combination therapy with Obinutuzumab in adult patients with chronic lymphocytic leukemia who have not previously received treatment Combination therapy with rituximab in adult patients with chronic lymphocytic leukemia who have previously received at least one treatment Monotherapy in adult patients with chronic lymphocytic leukemia that has relapsed due to or refractory to chemoimmuno therapy and B-cell receptor pathway inhibitors Acute myeloid leukemia Combination therapy with azacitidine or decitabine in adult patients who are newly diagnosed with acute myeloid leukemia, and who are 75 years of age or older or have a comorbidity that is not suitable for intensive induction chemotherapy
30	Imported	Venclexta tablet 50mg ((Venetoclax)				
31	Imported	Venclexta tablet 100mg (Venetoclax)				
32	Imported	Alunbrig tab.30mg (brigatinib)	Takeda Pharmaceuticals Korea Co., Ltd.	2020-08-27 (Orphan, switched to new drug) * First approval 2018-11-30	[04210] Antineoplastic drugs	Treatment of patients with anaplastic lymphoma kinase (ALK) positive progressive or metastatic non-small cell lung cancer
33	Imported	Alunbrig tab.90mg (brigatinib)				
34	Imported	Alunbrig tab.180mg (brigatinib)				

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

2.2. Approval Status of Orphan Drugs

As for chemical drugs approved in 2020, there were 14 new orphan drug items (14 imported items) (Refer to Table 27).

The approval of orphan drugs by classification code is as follows: 6 anticancer drug items, 6 miscellaneous central nervous system drug items, 1 miscellaneous circulatory system drug item, and 1 radio pharmaceutical drug item. From 8 ingredients of orphan drugs approved in 2020, all ingredients were newly designated in 2019 as ingredients of orphan drugs, except for “pitolisant hydrochloride.”

Table 27. Approval Status of Orphan Drug in 2020 (Chemical Drugs)

No.	Manufactured / Imported	Product	Company	Date of Approval	Class. Code	Efficacy/Effectiveness	Designation Status of Orphan Drugs	
1	Imported	Xospata tablet 40mg (Gilteritinib fumarate)	Astellas Pharma Korea, Inc.	2020-03-06	[421] Antineo-plastic drugs	Treatment of adult patients with relapsed or refractory acute myeloid leukemia who are positive for FLT3 mutation	No.	246 (Designated in 2019)
							Ing.	Gilteritinib fumarate (oral)
							Indication	Treatment of patients with relapsed or refractory acute myeloid leukemia who are positive for FLT3 mutation
2	Imported	Rozlytrek Capsule 100mg (Entrectinib)	Roche Korea Co., Ltd.	2020-04-21	[421] Antineo-plastic drugs	1. Used to treat solid cancer in adults and children 12 years of age or older with neurotrophic tyrosine receptor kinase (NTRK) gene fusion without known acquired resistant mutations 2. Local progressive or metastatic non-small cell lung carcinoma that is positive for ROS1 in adults The efficacy and effectiveness of this drug were approved based on the overall response rate, and there is no clinical study result that demonstrates clinical benefits such as an increase in the duration of survival.	No.	252 (Designated in 2019)
							Ing.	Entrectinib (oral)
							Indication	1. Local progressive or metastatic non-small cell lung carcinoma that is positive for ROS1 2. Treatment of local progressive or metastatic solid cancer in adults and children who must possess NTRK gene fusion without known acquired resistant mutations, are likely to have severe morbidity during surgical resection, and do not have suitable treatments which have been provided after the existing drug (or therapy) or are currently available
3	Imported	Rozlytrek Capsule 200mg (Entrectinib)						
4	Imported	VITRAKVI capsule 25mg (Larotrectinib sulfate)	Bayer Korea Ltd.	2020-05-11	[421] Antineo-plastic drugs	Treatment of local progressive or metastatic solid cancer in adults and children who must possess NTRK gene fusion without known acquired resistant mutations, are likely to have severe morbidity during surgical resection, and do not have suitable treatments which have been provided after the existing drug (or therapy) or are currently available	No.	255 (Designated in 2019)
							Ing.	Larotrectinib sulfate
							Indication	Treatment of local progressive or metastatic solid cancer in adults and children who must possess NTRK gene fusion without known acquired resistant mutations, are likely to have severe morbidity during surgical resection, and do not have suitable treatments which have been provided after the existing drug (or therapy) or are currently available
5	Imported	VITRAKVI oral solution (Larotrectinib sulfate)						
6	Imported	VITRAKVI capsule 100mg (Larotrectinib sulfate)						

7	Imported	Lutathera (Lutetium (177Lu) oxodotreotide)	Novartis Korea	2020-07-09	[431] Radio-pharma-ceutical	Treatment of adult gastroentero pancreatic neuroendocrine tumors (GEP-NET) that are positive for somatostatin receptor	No.	262 (Designated in 2019)
							Ing.	Lutetium oxodotreotide (Inj.)
							Indication	Treatment of adult gastroentero pancreatic neuroendocrine tumors (GEP-NET) that are positive for somatostatin receptor
8	Imported	Vyndamax® Capsules 61mg (tafamidis)	Pfizer Korea	2020-08-19	[219] Miscella-neous cardio-vascular drug	Vernal kerato conjunctivitis with giant papillary growth on the eyelid conjunctiva (when effect of anti-allergic drugs is insufficient)	No.	185 (additionally designated in 2019)
							Ing.	Tafamidis meglumine (oral)
							Indication	1. Transthyretin familial amyloid polyneuropathy 2. Transthyretin amyloid cardiomyopathy (cardiac amyloidosis)
9	Imported	AUSTEDO tab. 6mg (Deutetrabenazine)	Teva-Handok	2020-09-16	[119] Miscella-neous central nervous system drug	Improvement of symptoms of Huntington's chorea	No.	256 (Designated in 2019)
10	Imported	AUSTEDO tab. 9mg (Deutetrabenazine)					Ing.	Deutetrabenazine (oral)
11	Imported	AUSTEDO tab. 12mg (Deutetrabenazine)					Indication	Huntington's chorea
12	Imported	Evrysdi dry syrup 0.75mg/mL (Risdiplam)	Roche Korea Co., Ltd.	2020-11-02	[119] Miscella-neous central nervous system drug	Treatment 5q spinal muscular atrophy	No.	264 (Designated in 2019)
							Ing.	Risdiplam (oral)
							Indication	Spinal muscular atrophy
13	Imported	Wakix 5mg film-coated tablets (pitolisant hydrochloride)	Mitsubishi Tanabe Pharma Korea Co.,Ltd.	2020-12-30	[119] Miscella-neous central nervous system drug	Narcolepsy in adults accompanied or not accompanied by a cataplexy	No.	239 (Designated in 2018)
							Ing.	Pitolisant hydrochloride (oral)
14	Imported	Wakix 20mg film-coated tablets (pitolisant hydrochloride)					Indication	Treatment of narcolepsy in adults accompanied or not accompanied by a cataplexy

* Detailed approval information (efficacy/effectiveness, dosage/mode of administration, and precautions for use) is available at Drug Safety World (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 authorizes as incrementally modified or medicinally advanced for safety, efficacy, and usefulness (medication compliance, convenience, etc.) compared to approved (notified) drugs requiring data submission under Article 2(8) of the Regulations for Pharmaceutical Approval, Notification and Review.

The development types of incrementally modified drugs approved for the last 5 years are as follows: the development of combination drugs with new composition of active substances (drugs containing 2 or more active ingredients in one product) was noticeable from 2016 to 2017; and 6 SR tablet items with improved mode of administration/dosage by reducing the number of intakes were accepted as incrementally modified drugs in 2018. In 2019, 13 items with improved efficacy (11 items) and improved usability (2 items) were approved as incrementally modified drugs. In 2020, drugs with improved usability (5 items) including 4 SR tablet items with improved intake convenience and compliance by a change in the dosage form and mode of administration/ dosage, and 1 item of which efficacy improvement was recognized were approved as incrementally modified drugs (Refer to Table 28).

The detailed acceptance criteria for incrementally modified drugs (6 items) approved in 2020 are as follows: 4 peptic ulcer drug items in which usability (reduced total intake frequency: three times per day → twice a day) was recognized by improving the intake convenience and compliance as SR tablets with changes in dosage form and mode of administration/dosage, 1 X-ray contrast agent item in which usability improvement was recognized by improving final intake dose and taste to prevent nausea/vomiting, and 1 anti-tussive expectorant item in

which improved efficacy was verified by combining existing combination drugs compared to existing similar drugs.

Table 28. Type of Incrementally Modified Drugs in 2015-2020

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

Since November 2011, the MFDS has been publishing the *Incrementally Modified Drug Approval Casebook (Guide for Civil Petitioners)*, focusing on the current information and cases of incrementally modified drugs to ensure that the domestic pharmaceutical industry can refer to the Casebook for drug research and development. The status of incrementally modified drugs approved in 2020 is planned to be reflected in the Casebook, which will include approval status, status by product type, detailed acceptance criteria by case, unaccepted cases, etc.

Approval of incrementally modified drugs by acceptance criteria is as follows: drugs with improved efficacy (63 items, 55.8%) and increased treatment effects that are proven, and those with improved usability (39 items, 34.5%) resulting from improved dosage forms accounted for 90.3% of all incrementally modified drugs, followed by 7 items (6.2%) recognized for advanced pharmaceutical technology, and 4 items (3.5%) with improved safety (Figure 7).

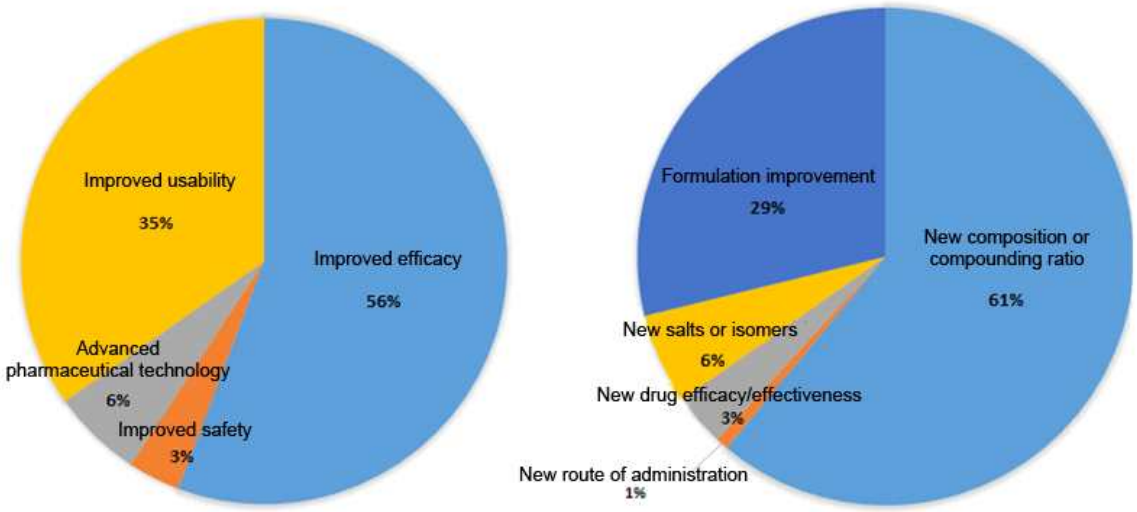

Figure 7. Approval Status on Incrementally Modified Drugs by Acceptance Criteria and by Type (2009-2020)

Table 29. List of Incrementally Modified Drugs (2009-2020)

No.	Product	Company	Date of Approval	Classification code	Remarks
1	Amosartan Tab. 5/50mg	Hanmi Pharm. Co., Ltd.	2009-03-31	[214] 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	[141] Antihistamines	Salt and dosage form changes
6	CLANZA CR Tab. (Aceclofenac)	Korea United Pharm. Inc.	2010-04-14	[114] Antipyretics, analgesics, and anti-inflammatory drugs	Change in dosage form, strength and mode of administration/dosage
7	Ridrone plus tablet	Pacific Pharmaceuticals	2010-06-23	[399] Miscellaneous metabolic drugs	Change of active substance type or compounding ratio
8	RISENEX-PLUS Tab.	HANLIM PHARM. CO., LTD.	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	[214] 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	[114] Antipyretics, analgesics, and anti-inflammatory drugs	Change in dosage form, strength and mode of administration/dosage
13	ROXFEN CR Tablet	SHIN POONG PHARM. CO., LTD.	2011-03-18	[114] Antipyretics, analgesics, and anti-inflammatory drugs	Change in dosage form, strength and mode of administration/dosage
14	Pletaal SR Capsules	Korea Otsuka Pharmaceutical	2011-04-19	[339] 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	[421] Antineoplastic drugs	Change in strength and mode of administration/dosage
16	Ridonel D Tab.	Hanmi Pharm. Co., Ltd.	2012-04-03	[399] 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	[232] Peptic ulcer drugs	New salts or isomers (first in Korea)

No.	Product	Company	Date of Approval	Classification code	Remarks
19	Nasaflex Nasal Spray	HANLIM PHARM. CO., LTD.	2012-11-16	[132] Otic and nasal drugs	Change of active substance type 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	[214] Antihypertensives	Change of active substance type or compounding ratio
22	KanarbPlus Tablet 60/12.5mg				
23	Olmetan Tab. 22.08mg (olmesartan cilexetil)	JINYANG PHARM CO.,LTD.	2013-01-31	[214] 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	[339] 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	[259] Miscellaneous urogenital and anal organ drugs	Add an apparently different efficacy/effectiveness
29	Nenoma Tablet 15mg (Clomipramine HCl)	Huons Co., Ltd.			
30	Condencia Tab. 15mg (Clomipramine HCl)	CTCBIO INC.			
31	Clojac Tab. (clomipramine hydrochloride)	JINYANG PHARM CO.,LTD.			
32	VOGMET Tablet 0.2/250mg	CJ Cheiljedang Corp. → (name change)HK inno.N	2013-06-17	[396] Antidiabetic drugs	Change of active substance type or compounding ratio
33	VOGMET Tablet 0.2/500mg				
34	Bonviva Plus Tablet	Dreampharma Corp. → (name change) Alvogen Korea Co., Ltd.	2013-07-08	[399] Miscellaneous metabolic drugs	Change of active substance type or compounding ratio
35	Levacalm Tab. 20/160mg	LG Life Science→ (name change) LG Chem Ltd.	2013-07-25	[214] Antihypertensives	Change of active substance type 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	[396] Antidiabetic drugs	Change of active substance type or compounding ratio
39	Dexid Tab 480mg (r-thioctic acid tromethamine)	Bukang Pharm Co.,Ltd	2013-11-21	[399] 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	[396] Antidiabetic drugs	Change of active substance type or compounding ratio

No.	Product	Company	Date of Approval	Classification code	Remarks
41	Sapodifil SR Tablet 300mg (Sarpogrelate hydrochloride)	Alvogen Korea Co., Ltd.	2015-01-23	[339] 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	[114] Antipyretics, analgesics, and anti-inflammatory drugs	Change in dosage form, strength and mode of administration/dosage
47	Tenelia M SR tab. 10/750mg	Handok Inc.	2015-03-31	[396] Antidiabetic drugs	Change of active substance type 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	[122] 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	[396] Antidiabetic drugs	Change of active substance type or compounding ratio
56	Sugamet XR Tablet 2.5/500 mg	DONG-A ST	2015-12-31	[396] Antidiabetic drugs	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	[214] Antihypertensives	Change of active substance type or compounding ratio
60	Dukarb Tablet 30/10mg				
61	Dukarb Tablet 60/5mg				
62	Dukarb Tablet 60/10mg				

No.	Product	Company	Date of Approval	Classification code	Remarks
63	Karbpine Tab. 60/5mg	Boryung Biopharma Co., Ltd.	2016-05-31	[214] Antihypertensives	Change of active substance type 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	[214] Antihypertensives	Change of active substance type 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	[214] Antihypertensives	Change of active substance type 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	[396] Antidiabetic drugs	Change of active substance type 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	[239] Miscellaneous digestive organ 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	[396] Antidiabetic drugs	Change of active substance type or compounding ratio
78	Duvimet XR Tab. 0.25/500mg	Chong Kun Dang Pharm.	2016-09-01	[396] Antidiabetic drugs	Change of active substance type or compounding ratio
79	LIPORAXEL SOLUTION (PACLITAXEL)	DAEHWA PHARMACEUTICAL., LTD.	2016-09-09	[421] Antineoplastic drugs	New route of administration
80	Safrep Solution	CTCBIO INC.	2016-10-06	[721] X-ray contrast agent	Change of active substance type or compounding ratio
81	Duocolon Solution	Alvogen Korea Co., Ltd.	2016-10-06	[721] X-ray contrast agent	Change of active substance type or compounding ratio
82	Coolipa Sol.	Ahngook Pharm.	2016-10-06	[721] X-ray contrast agent	Change of active substance type or compounding ratio
83	Surfolase CR Tablet (Acebrophylline)	Hyundai Pharm	2017-02-24	[229] 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	[222] Antitussive expectorants	Change in dosage form, strength and mode of administration/dosage
85	Levocare CR Tablets (Levodropropizine)	Kwangdong Pharm, Ltd.	2017-04-12	[222] Antitussive expectorants	Change in dosage form, strength and mode of administration/dosage

No.	Product	Company	Date of Approval	Classification code	Remarks
86	Neotuss SR Tab. (Levodropropizine)	JW Shinyak	2017-04-12	[222] 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	[214] Antihypertensives	Change of active substance type or compounding ratio
88	Amosartan Plus Tab. 5/100/12.5mg				
89	Amosartan Plus Tab. 5/100/25mg				
90	TWOTOPSPLUS Tab. 40/5/12.5 mg	ILDONG PHARMACEUTICAL CO., LTD.	2017-07-25	[214] Antihypertensives	Change of active substance type 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	[141] 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	[721] X-ray contrast agent	Change of active substance type or compounding ratio
101	STAFEN Cap.	HANLIM PHARM. CO., LTD.	2019-04-03	[218] Drugs for atherosclerosis	Change of active substance type or compounding ratio
102	Neustatin-Duo Capsule	Samjin Pharmaceutical Co., Ltd.	2019-04-03	[218] Drugs for atherosclerosis	Change of active substance type or compounding ratio
103	Pitalone-F Cap.	DongKook Pharmaceutical Co., Ltd.	2019-04-03	[218] Drugs for atherosclerosis	Change of active substance type or compounding ratio
104	Pevaro-F Cap.	Ahngook Pharm.	2019-04-03	[218] Drugs for atherosclerosis	Change of active substance type or compounding ratio
105	Liloufen Cap.	GL Pharma	2019-04-03	[218] Drugs for atherosclerosis	Change of active substance type or compounding ratio
106	Uptava Cap.	Daewon Pharm. Co., Ltd	2019-04-03	[218] Drugs for atherosclerosis	Change of active substance type or compounding ratio
107	Lipestin Cap.	Korea Prime Pharm. Co., Ltd.	2019-04-03	[218] Drugs for atherosclerosis	Change of active substance type or compounding ratio

No.	Product	Company	Date of Approval	Classification code	Remarks
108	PF Capsule.	Dong Kwang Pharm. Co.,Ltd.	2019-04-03	[218] Drugs for atherosclerosis	Change of active substance type or compounding ratio
109	Orafang Tab.	Pharmbio Korea Inc.	2019-04-11	[721] X-ray contrast agent	Change of active substance type or compounding ratio
110	True Set Tablet 40/5/12.5mg	Yuhan Corporation	2019-08-23	[214] Antihypertensives	Change of active substance type 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	[721] X-ray contrast agent	Change of active substance type or compounding ratio
114	Codaewon S syrup	Daewon Pharm. Co., Ltd	2020-07-15	[222] Antitussive expectorants	Change of active substance type or compounding ratio
115	Recomid SR tablet(Rebamipide)	Yuhan Corporation	2020-12-16	[232] Peptic ulcer drugs	Change in dosage form, strength and mode of administration/dosage
116	Mucotect SR Tab.	GC Pharma	2020-12-16	[232] Peptic ulcer drugs	Change in dosage form, strength and mode of administration/dosage
117	MUCOTRA SR tab	DAEWOONG PHARMACEUTICAL CO.,LTD.	2020-12-16	[232] Peptic ulcer drugs	Change in dosage form, strength and mode of administration/dosage
118	Bidreba SR 150mg	Daewon Pharm. Co., Ltd	2020-12-16	[232] Peptic ulcer drugs	Change in dosage form, strength and mode of administration/dosage

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

2.4. Approval Status of Drugs Requiring Data Submission

Drugs requiring data submission are those that are not new drugs, but need to be evaluated for safety and efficacy, and include ▲drugs that contain new salts (isomers) as an active substance, ▲drugs belonging to new therapeutic classes, ▲active substance with new composition or change in strength, ▲drugs with new administration routes, ▲drugs with new administration/ dosage, ▲new dosage form (same administration route).

Among the drugs requiring data submission (excluding 6 incrementally modified drug items) approved in 2020, the development of drugs with new composition or changes in strength composed the largest portion of items (63.8%, 208 items), followed by drugs with new salts or isomers

(22.4%, 73 items) (Refer to Table 30).

Table 30. Approval Status of Drugs Requiring Data Submission in 2020

Review Type of Drugs Requiring Data Submission		No. of Approved Items	
New salts or isomers		74	
New drug efficacy group		2	
New composition of active substance or change only in strength	208	New composition	182
		Change in strength	26
New mode of administration/dosage		3	
New dosage form (same route of administration)		39	
Total		326	

* Excluding incrementally modified drugs (drugs requiring data submission)

1) New salts or isomers drugs (74 items)

Chemical drugs approved as new salts or isomers include 74 items (71 manufactured items, 3 imported items). The number of approved antidiabetic drugs were more than 2/3 (70.3%) of the new salts and isomer drugs approved in 2020, where most of the items (37 items, 50.7%) were drugs developed with new salts from a previously approved antidiabetic drug, dapagliflozin propanediol hydrate, 9 items (12.2%) were drugs where teneligliptin hydrobromide hydrate was changed into teneligliptin hydrochloride hydrate, and 5 items (6.8%) were drugs where sitagliptin phosphate hydrate was changed into sitagliptin hydrochloride hydrate.

Other approved drugs include 11 items in which tofacitinib citrate, a

treatment for rheumatoid arthritis and psoriasis arthritis, was developed as new salts, eight items in which desvenlafaxine succinate monohydrate, a treatment for depression, was developed as new salts, and one item in which melphalan, a treatment for multiple myeloma, was changed into melphalan hydrochloride (Refer to Table 31).

Table 31. Approval Status of Drugs with New Salt or New Isomer that Require Data Submission in 2020

No.	Manufactured/ Imported	Product	Company	Date of Approval	Class. Code	Efficacy/Effectiveness (partially summarized)	Remarks
1	Manufactured	VIATIN Tab. 100mg (sitagliptin hydrochloride hydrate)	Korea United Pharm. Inc.	2020-01-03	[396] Anti-diabetic drug	Adjuvant drug for diet therapy and exercise therapy in type 2 diabetes patients	Phosphate hydrate → hydrochloride hydrate
2	Manufactured	Vildagle Tab. 50mg (vildagliptin hydrochloride)	Hanmi Pharm. Co., Ltd.	2020-01-21	[396] Anti-diabetic drug	Adjuvant drug for diet therapy and exercise therapy in type 2 diabetes patients	Hydro* chloride
3	Imported	Megval Injection 50mg (Melphalan hydrochloride)	Acepharma	2020-01-23	[421] Antineo-plastic drugs	Multiple myeloma	Hydro* chloride
4	Manufactured	Janulitin Alpha Tab. 25mg (Sitagliptin Hydrochloride Hydrate)	Daewon Pharm. Co., Ltd	2020-03-31	[396] Anti-diabetic drug	Adjuvant drug for diet therapy and exercise therapy in type 2 diabetes patients	Phosphate → hydro-chloride
5	Manufactured	Janulitin Alpha Tab. 50mg (Sitagliptin Hydrochloride Hydrate)					
6	Manufactured	Dapozin Tablet 10mg (Dapagliflozin)	Samjin Pharmaceutical Co., Ltd.	2020-04-02	[396] Anti-diabetic drug	Adjuvant drug for diet therapy and exercise therapy in type 2 diabetes patients	Propanediol hydrate → dapagliflozin
7	Manufactured	DESVERA Extended-Release Tablets 100mg (Desvenlafaxine benzoate)	NEXPHARM KOREA CO., LTD.	2020-04-07	[117] Psycho-tropics	Depression	Succinate monohydrate → Benzoate
8	Manufactured	DESVERA Extended-Release Tablets 50mg (Desvenlafaxine benzoate)					

No.	Manufactured/ Imported	Product	Company	Date of Approval	Class. Code	Efficacy/Effectiveness (partially summarized)	Remarks
9	Manufactured	S-Ven Extended-Release Tablet 100mg (Desvenlafaxine Benzoate)	MYUNG IN PHARM	2020-04-07	[117] Psycho-tropics	Depression	Succinate monohydrate → Benzoate
10	Manufactured	S-Ven Extended-Release Tablet 50mg (Desvenlafaxine Benzoate)					
11	Manufactured	PRINEXOR ER Tab. 100mg (Desvenlafaxine Benzoate)	HANLIM PHARM. CO., LTD.	2020-04-07	[117] Psycho-tropics	Depression	Succinate monohydrate → Benzoate
12	Manufactured	PRINEXOR ER Tab. 50mg (Desvenlafaxine Benzoate)					
13	Manufactured	Defaxine SR Tablet 100mg (Desvenlafaxine)	Whan In Pharm. Co., Ltd.	2020-04-07	[117] Psycho-tropics	Depression	Succinate monohydrate → Benzoate
14	Manufactured	Defaxine SR Tablet 50mg (Desvenlafaxine)					
15	Manufactured	Dapazin Tab. 10mg (Dapagliflozin Bis L-proline)	KyungDong pharm. co., Ltd	2020-05-22	[396] Anti-diabetic drug	Adjuvant drug for diet therapy and exercise therapy in type 2 diabetes patients	Propanediol hydrate → Bis L-proline
16	Manufactured	Boryung Dapagliflozin Tablet 10mg Dapagliflozin Bis L-proline)	Boryung Pharmaceutical	2020-05-22	[396] Anti-diabetic drug	Adjuvant drug for diet therapy and exercise therapy in type 2 diabetes patients	Propanediol hydrate → Bis L-proline
17	Manufactured	DAFOR Tab. 10 mg (Dapagliflozin Bis L-prolin)	ILDONG PHARMACEUTICAL CO., LTD.	2020-05-22	[396] Anti-diabetic drug	Adjuvant drug for diet therapy and exercise therapy in type 2 diabetes patients	Propanediol hydrate → Bis L-proline
18	Manufactured	Jeforga Tablet 10mg (dapagliflozin Bis L-proline)	Jeil Pharmaceutical Co., Ltd.	2020-05-22	[396] Anti-diabetic drug	Adjuvant drug for diet therapy and exercise therapy in type 2 diabetes patients	Propanediol hydrate → Bis L-proline
19	Manufactured	CKD dapagliflozin Tab. 10mg	Chong Kun Dang Pharm.	2020-05-28	[396] Anti-diabetic drug	Adjuvant drug for diet therapy and exercise therapy in type 2 diabetes patients	Propanediol hydrate → dapagliflozin
20	Manufactured	CKD dapagliflozin Tab. 5mg					

No.	Manufactured/ Imported	Product	Company	Date of Approval	Class. Code	Efficacy/Effectiveness (partially summarized)	Remarks
21	Manufactured	Podabe Tab. 10mg (Dapagliflozin)	LitePharmTech	2020-06-17	[396] Anti-diabetic drug	Adjuvant drug for diet therapy and exercise therapy in type 2 diabetes patients	Propanediol hydrate → dapagliflozin
22	Manufactured	Rosiga Tab. 10mg (Dapagliflozin)	ILHWA CO., LTD	2020-06-17	[396] Anti-diabetic drug	Adjuvant drug for diet therapy and exercise therapy in type 2 diabetes patients	Propanediol hydrate → dapagliflozin
23	Manufactured	Pharma Dapagliflozin Tab. 10mg(Dapagliflozin)	Korea Pharma Co., Ltd.	2020-06-17	[396] Anti-diabetic drug	Adjuvant drug for diet therapy and exercise therapy in type 2 diabetes patients	Propanediol hydrate → dapagliflozin
24	Manufactured	Pasiga Tablet 10mg (Dapagliflozin)	Pharvis Korea Pharm Co., Ltd.	2020-06-17	[396] Anti-diabetic drug	Adjuvant drug for diet therapy and exercise therapy in type 2 diabetes patients	Propanediol hydrate → dapagliflozin
25	Manufactured	Dipaclo Tab. 10mg (Dapagliflozin)	Samik Pharm	2020-06-17	[396] Anti-diabetic drug	Adjuvant drug for diet therapy and exercise therapy in type 2 diabetes patients	Propanediol hydrate → dapagliflozin
26	Manufactured	Daforga tab. 10mg (Dapagliflozin)	Sam Chun Dang Pharm. Co.,Ltd.	2020-06-17	[396] Anti-diabetic drug	Adjuvant drug for diet therapy and exercise therapy in type 2 diabetes patients	Propanediol hydrate → dapagliflozin
27	Manufactured	Forxizin Tab. (Dapagliflozin)	WITHUS PHARMACEUTICAL CO., LTD.	2020-06-17	[396] Anti-diabetic drug	Adjuvant drug for diet therapy and exercise therapy in type 2 diabetes patients	Propanediol hydrate → dapagliflozin
28	Manufactured	Forxuga Tab 10mg (Dapaglifozin)	Reyon Pharmaceutical Co., Ltd.	2020-06-17	[396] Anti-diabetic drug	Adjuvant drug for diet therapy and exercise therapy in type 2 diabetes patients	Propanediol hydrate → dapagliflozin
29	Manufactured	Forgli Tab. (Dapagliflozin)	Korea Prime Pharm. Co., Ltd.	2020-06-17	[396] Anti-diabetic drug	Adjuvant drug for diet therapy and exercise therapy in type 2 diabetes patients	Propanediol hydrate → dapagliflozin

No.	Manufactured/ Imported	Product	Company	Date of Approval	Class. Code	Efficacy/Effectiveness (partially summarized)	Remarks
30	Imported	Spravato Nasal Spray (esketamine hydrochloride)	Janssen Korea Ltd.	2020-06-23	[117] Psycho-tropics	Depression	Isomer (S type)
31	Manufactured	Dapagen Tab. 10mg (dapagliflozin anhydrous lactose mixture)	Theragen Etex Co., Ltd.	2020-07-23	[396] Anti-diabetic drug	Adjuvant drug for diet therapy and exercise therapy in type 2 diabetes patients	Propanediol hydrate → anhydrous lactose mixture
32	Manufactured	Dapagen Tab. 5mg (dapagliflozin anhydrous lactose mixture)					
33	Manufactured	ForxiD tab. 10mg (dapagliflozin anhydrous lactose mixture)	KUKJE PHARMA Co., Ltd.	2020-07-23	[396] Anti-diabetic drug	Adjuvant drug for diet therapy and exercise therapy in type 2 diabetes patients	Propanediol hydrate → anhydrous lactose mixture
34	Manufactured	ForxiD tab. 5mg (dapagliflozin anhydrous lactose mixture)					
35	Manufactured	Daflo Tab. 10mg (dapagliflozin anhydrous lactose mixture)	Dong Kwang Pharm. Co.,Ltd.	2020-07-23	[396] Anti-diabetic drug	Adjuvant drug for diet therapy and exercise therapy in type 2 diabetes patients	Propanediol hydrate → anhydrous lactose mixture
36	Manufactured	Daflo Tab. 5mg (dapagliflozin anhydrous lactose mixture)					
37	Manufactured	Dapeulzin Tab. 10mg (dapagliflozin anhydrous lactose mixture)	DongKook Pharmaceutical Co., Ltd.	2020-07-23	[396] Anti-diabetic drug	Adjuvant drug for diet therapy and exercise therapy in type 2 diabetes patients	Propanediol hydrate → anhydrous lactose mixture
38	Manufactured	Dapeulzin Tab. 5mg (dapagliflozin anhydrous lactose mixture)					
39	Manufactured	DONGWHA Dapagliflozin Tab. 10 mg (dapagliflozin anhydrous lactose mixture)	DONGWHA PHARM. CO., LTD.	2020-07-23	[396] Anti-diabetic drug	Adjuvant drug for diet therapy and exercise therapy in type 2 diabetes patients	Propanediol hydrate → anhydrous lactose mixture
40	Manufactured	DONGWHA Dapagliflozin Tab. 5 mg (dapagliflozin anhydrous lactose mixture)					
41	Manufactured	Focigli Tab. 10 mg (dapagliflozin anhydrous lactose mixture)	Sinil Pharmaceutical Co., Ltd.	2020-07-23	[396] Anti-diabetic drug	Adjuvant drug for diet therapy and exercise therapy in type 2 diabetes patients	Propanediol hydrate → anhydrous lactose mixture
42	Manufactured	Focigli Tab. 5 mg (dapagliflozin anhydrous lactose mixture)					

No.	Manufactured/ Imported	Product	Company	Date of Approval	Class. Code	Efficacy/Effectiveness (partially summarized)	Remarks
43	Manufactured	Dapaelson Tab. 5mg (dapagliflozin anhydrous lactose mixture)	Elyson Pharmaceuti-cal Co., LTD	2020-07-23	[396] Anti-diabetic drug	Adjuvant drug for diet therapy and exercise therapy in type 2 diabetes patients	Propanediol hydrate → anhydrous lactose mixture
44	Manufactured	Dapaelson Tab. 10mg (dapagliflozin anhydrous lactose mixture)					
45	Manufactured	Yungjin Dapagliflozin Tab. 10mg (Dapagliflozin Anhydrous Mixture)	Yungjin Pharm.	2020-07-23	[396] Anti-diabetic drug	Adjuvant drug for diet therapy and exercise therapy in type 2 diabetes patients	Propanediol hydrate → anhydrous lactose mixture
46	Manufactured	Yungjin Dapagliflozin Tab. 5mg (Dapagliflozin Anhydrous Mixture)					
47	Manufactured	DAFLOZIN Tab. 10mg (Dapagliflozin Anhydrous Mixture)	Wooridul Pharmaceuti cal Ltd.→ (name change)PharmGen Science Inc.	2020-07-23	[396] Anti-diabetic drug	Adjuvant drug for diet therapy and exercise therapy in type 2 diabetes patients	Propanediol hydrate → anhydrous lactose mixture
48	Manufactured	DANGXIGA TAB. 10mg (Dapagliflozin Anhydrous Mixture)	HUTECS KOREA PHARMACE UTICAL CO., LTD	2020-07-23	[396] Anti-diabetic drug	Adjuvant drug for diet therapy and exercise therapy in type 2 diabetes patients	Propanediol hydrate → anhydrous lactose mixture
49	Manufactured	DANGXIGA TAB. 5mg (Dapagliflozin Anhydrous Mixture)					
50	Manufactured	Forxilozin Tablets 10mg (Dapagliflozin anhydrous lactose mixture)	Han Wha Pharma Co., Ltd.	2020-07-23	[396] Anti-diabetic drug	Adjuvant drug for diet therapy and exercise therapy in type 2 diabetes patients	Propanediol hydrate → anhydrous lactose mixture
51	Manufactured	Forxilozin Tablets 5mg (Dapagliflozin anhydrous lactose mixture)					
52	Manufactured	Boryung Tofacitinib Tablet 5mg (Tofacitinib aspartate)	Boryung Pharmaceutic al	2020-08-27	[142] Non-specific immuno-gen preparati ons	Rheumatoid arthritis, psoriatic arthritis	Citrate→ Aspartate
53	Manufactured	Tenelitin Tab. 20mg (Teneligliptin Hydrochloride Hydrate)	KyungDong pharm. co., Ltd	2020-09-04	[396] Anti-diabetic drug	Adjuvant drug for diet therapy and exercise therapy in type 2 diabetes patients	Hydro-bromide hydrate→ Hydrochloride hydrate
54	Manufactured	Topaks Tab. 5mg (Tofacitinib)	LitePharmTec h	2020-09-07	[142] Non-specific immuno-gen preparati ons	Rheumatoid arthritis, psoriatic arthritis	Citrate → Tofacitinib

No.	Manufactured/ Imported	Product	Company	Date of Approval	Class. Code	Efficacy/Effectiveness (partially summarized)	Remarks
55	Manufactured	Tofacia Tab. (Tofacitinib)	KIMS Pharmaceutical Co., Ltd.	2020-09-07	[142] Non-specific immuno-gen preparations	Rheumatoid arthritis, psoriatic arthritis	Citrate → Tofacitinib
56	Manufactured	Xelfanic Tab. 5mg (Tofacitinib)	Samik Pharm	2020-09-07	[142] Non-specific immuno-gen preparations	Rheumatoid arthritis, psoriatic arthritis	Citrate → Tofacitinib
57	Manufactured	Tocinib Tab 5mg (Tofacitinib)	SK Chemicals	2020-09-07	[142] Non-specific immuno-gen preparations	Rheumatoid arthritis, psoriatic arthritis	Citrate → Tofacitinib
58	Manufactured	XELFATINIB TAB. 5mg (Tofacitinib)	INIST BIO PHARMACEUTICAL CO., LTD. → (name change)VIVOZON PHARMACEUTICAL CO., LTD.	2020-09-07	[142] Non-specific immuno-gen preparations	Rheumatoid arthritis, psoriatic arthritis	Citrate → Tofacitinib
59	Manufactured	IL-YANG Tofacitinib Tab. 5mg (Tofacitinib)	IL-YANG PHARMACEUTICAL CO., LTD	2020-09-07	[142] Non-specific immuno-gen preparations	Rheumatoid arthritis, psoriatic arthritis	Citrate → Tofacitinib
60	Manufactured	Xelzone tab. 5mg (Tofacitinib)	Hana pharm	2020-09-07	[142] Non-specific immuno-gen preparations	Rheumatoid arthritis, psoriatic arthritis	Citrate → Tofacitinib
61	Manufactured	Tofaxel Tab. 5mg (Tofacitinib)	Korea Prime Pharm. Co., Ltd.	2020-09-07	[142] Non-specific immuno-gen preparations	Rheumatoid arthritis, psoriatic arthritis	Citrate → Tofacitinib

No.	Manufactured/ Imported	Product	Company	Date of Approval	Class. Code	Efficacy/Effectiveness (partially summarized)	Remarks
62	Manufactured	JAKFAS Tab. 5mg (Tofacitinib)	HANLIM PHARM. CO., LTD.	2020-09-07	[142] Non-specific immuno-gen preparati ons	Rheumatoid arthritis, psoriatic arthritis	Citrate → Tofacitinib
63	Manufactured	XELTOFA TAB 5mg (Tofacitinib aspartate (micronised))	DAEWOONG PHARMACE -UTICAL CO.,LTD.	2020-09-10	[142] Non-specific immuno-gen preparati ons	Rheumatoid arthritis, psoriatic arthritis	Citrate→ Aspartate
64	Imported	Pakis tab (Rasagiline tartrate)	Kyongbo pharma	2020-09-21	[119] Miscella-neous central nervous system agents	Treatment of Parkinson's disease	Mesilate → Tartrate
65	Manufactured	SITAX TABLETS 25mg (SITAGLIPTIN HYDROCHLORIDE)	GENUONE Sciences Inc.	2020-11-03	[396] Anti-diabetic drug	Adjuvant drug for diet therapy and exercise therapy in type 2 diabetes patients	Phosphate hydrate→ Hydrochloride hydrate
66	Manufactured	SITAX TABLETS 50mg (SITAGLIPTIN HYDROCHLORIDE)					
67	Manufactured	Tennella Tab. 20 mg (Teneligliptin hydrobromide hydrate)	Dalim Biotech	2020-11-05	[396] Anti-diabetic drug	Adjuvant drug for diet therapy and exercise therapy in type 2 diabetes patients	Hydro-bromide hydrate → Hydrochloride hydrate
68	Manufactured	Teneglip Tab. 20 mg (sitagliptin hydrochloride hydrate)	Mother's Pharmaceuti cal Co., Ltd.	2020-11-05	[396] Anti-diabetic drug	Adjuvant drug for diet therapy and exercise therapy in type 2 diabetes patients	Hydro-bromide hydrate → Hydrochloride hydrate
69	Manufactured	Teneglitin Tablet 20mg (Teneligliptin hydrobromide hydrate)	Pharvis Korea Pharm Co., Ltd.	2020-11-05	[396] Anti-diabetic drug	Adjuvant drug for diet therapy and exercise therapy in type 2 diabetes patients	Hydro-bromide hydrate → Hydrochloride hydrate
70	Manufactured	TenelD Tab. 20mg (Teneligliptin hydrobromide hydrate)	KUKJE PHARMA Co., Ltd.	2020-11-05	[396] Anti-diabetic drug	Adjuvant drug for diet therapy and exercise therapy in type 2 diabetes patients	Hydro-bromide hydrate → Hydrochloride hydrate

No.	Manufactured/ Imported	Product	Company	Date of Approval	Class. Code	Efficacy/Effectiveness (partially summarized)	Remarks
71	Manufactured	Tedi-4 tab. 20mg (Teneligliptin hydrobromide hydrate)	Dong Kwang Pharm. Co.,Ltd.	2020-11-05	[396] Anti-diabetic drug	Adjuvant drug for diet therapy and exercise therapy in type 2 diabetes patients	Hydro-bromide hydrate → Hydrochloride hydrate
72	Manufactured	Telia tab. 20mg (Teneligliptin hydrobromide hydrate)	Sam Chun Dang Pharm. Co.,Ltd.	2020-11-05	[396] Anti-diabetic drug	Adjuvant drug for diet therapy and exercise therapy in type 2 diabetes patients	Hydro-bromide hydrate → Hydrochloride hydrate
73	Manufactured	TENESE TABLET 20mg (Teneligliptin hydrobromide hydrate)	AJU PHARM CO., LTD.	2020-11-05	[396] Anti-diabetic drug	Adjuvant drug for diet therapy and exercise therapy in type 2 diabetes patients	Hydro-bromide hydrate → Hydrochloride hydrate
74	Manufactured	JENELIA Tab. 20mg (Teneligliptin hydrobromide hydrate)	HANLIM PHARM. CO., LTD.	2020-11-05	[396] Anti-diabetic drug	Adjuvant drug for diet therapy and exercise therapy in type 2 diabetes patients	Hydro-bromide hydrate → Hydrochloride hydrate

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

2) Drugs with new efficacy group (2 items)

Chemical drugs approved for the new efficacy group included 2 imported items, which are plaque psoriasis treatments for adult patients subject to systemic therapy in which the active ingredient is dimethyl fumarate. They are drugs that changed the efficacy/effectiveness of already approved (notified) treatments for relapsing-remitting multiple sclerosis (Refer to Table 32).

Table 32. Approval Status of Drugs in New Therapeutic Class that Require Data Submission in 2020

No.	Manufactured / Imported	Product	Company	Date of Approval	Classification Code	Efficacy/ Effectiveness (partially summarized)
1	Imported	Skilarence 120mg Gastro-Resistant Tablet (Dimethyl fumarate)	KOLON Pharma	2020-05-14	[01420] Non-specific immunogen preparations	Plaque psoriasis treatment drug
2	Imported	Skilarence 30mg Gastro-Resistant Tablet (Dimethyl fumarate)				

3) Drugs with new composition of active substance or change only in strength (208 items)

In the case of drugs with new compositions, 182 were approved (176 manufactured items and 6 imported items), with cardiovascular drugs accounting for the majority (175 items, 96.2%). Among the approved drugs with new compositions, 98 items (53.4%) were the hypertension/ hyperlipidemia combinations, 80 items (44.0%) were combinations containing rosuvastatin calcium, and 74 items (40.7%) were hyperlipidemia combinations that all contain rosuvastatin calcium. Combinations containing rosuvastatin calcium (for hypertension/hyperlipidemia or hyperlipidemia) included 154 items, accounting for more than 4/5 (84.6%) of the drugs

with new composition approved in 2020 (Refer to Table 33).

Also, 26 new drugs with changes in strength (24 manufactured items, 2 imported items) were approved, where the majority of items (17 items, 65.4%) were SR tablets that increased the strength of the previously approved Tamsulosin Hydrochloride SR Tablet 0.2 mg into 0.4 mg (Refer to Table 34).

Table 33. Approval Status of Drugs with New Composition that Require Data Submission in 2020

No.	Manufactured/ Imported	Product	Company	Date of Approval	Classification Code	Active Ingredient
1	Manufactured	OLOMAX Tablet 40/5/10mg	DAEWOONG PHARMACEUTICAL CO.,LTD.	2020-02-06	[219] Miscellaneous cardiovascular drugs	Rosuvastatin Calcium, Amlodipine Besylate, Olmesartan Medoxomil
2	Manufactured	Candedipine Tab 16/10mg	GC Pharma	2020-02-14	[214] Anti-hypertensives	Candesartan Cilexetil, Amlodipine Besylate
3	Manufactured	Candedipine Tab 16/5mg				
4	Manufactured	Candedipine Tab 8/5mg				
5	Manufactured	OLOMAX Tablet 40/5/5mg	DAEWOONG PHARMACEUTICAL CO.,LTD.	2020-02-19	[219] Miscellaneous cardiovascular drugs	Rosuvastatin Calcium, Amlodipine Besylate, Olmesartan Medoxomil
6	Manufactured	TR Duo Tab. 40/20mg	Binex Co., Ltd.	2020-02-19	[219] Miscellaneous cardiovascular drugs	Telmisartan, Rosuvastatin Calcium
7	Manufactured	TR Duo Tab. 80/20mg				
8	Manufactured	MISARTANSTAR Tab. 40/10mg	Reyon Pharmaceutical Co., Ltd.	2020-02-19	[219] Miscellaneous cardiovascular drugs	Telmisartan, Rosuvastatin Calcium
9	Manufactured	MISARTANSTAR Tab. 40/20mg				
10	Manufactured	MISARTANSTAR Tab. 40/5mg				
11	Manufactured	MISARTANSTAR Tab. 80/10mg				
12	Manufactured	MISARTANSTAR Tab. 80/20mg	Reyon Pharmaceutical Co., Ltd.	2020-02-19	[219] Miscellaneous cardiovascular drugs	Telmisartan, Rosuvastatin Calcium
13	Manufactured	MISARTANSTAR Tab. 80/5mg				
14	Imported	Dovato Tablet	GlaxoSmithKline	2020-03-16	[629] Miscellaneous chemo-therapeutics	Lamivudine, Dolutegravir Sodium (micronised)

No.	Manufactured/ Imported	Product	Company	Date of Approval	Classification Code	Active Ingredient
15	Manufactured	TELOSTIN TAB. 40/10MG	DAEHWA PHARMACEUTICAL., LTD.	2020-03-17	[219] Miscellaneous cardiovascular drugs	Telmisartan, Rosuvastatin Calcium
16	Manufactured	TELOSTIN TAB. 40/20MG				
17	Manufactured	TELOSTIN TAB. 40/5MG				
18	Manufactured	TELOSTIN TAB. 80/10MG				
19	Manufactured	TELOSTIN TAB. 80/20MG				
20	Manufactured	TELOSTIN TAB. 80/5MG				
21	Manufactured	TELSARTAN R Tablets 40/10mg	DONGWHA PHARM. CO., LTD.	2020-03-17	[219] Miscellaneous cardiovascular drugs	Telmisartan, Rosuvastatin Calcium
22	Manufactured	TELSARTAN R Tablets 40/5mg				
23	Manufactured	TELSARTAN R Tablets 80/10mg				
24	Manufactured	TELSARTAN R Tablets 80/5mg				
25	Manufactured	Telmirobe Tab. 40/10mg	Myungmoon Pharm. Co., Ltd.	2020-03-17	[219] Miscellaneous cardiovascular drugs	Telmisartan, Rosuvastatin Calcium
26	Manufactured	Telmirobe Tab. 40/20mg				
27	Manufactured	Telmirobe Tab. 40/5mg				
28	Manufactured	Telmirobe Tab. 80/10mg				
29	Manufactured	Telmirobe Tab. 80/20mg				
30	Manufactured	Telmirobe Tab. 80/5mg				
31	Manufactured	Tellow Tab. 40/10mg	UNION KOREA PHARM	2020-03-17	[219] Miscellaneous cardiovascular drugs	Telmisartan, Rosuvastatin Calcium
32	Manufactured	Tellow Tab. 40/20mg				
33	Manufactured	Tellow Tab. 40/5mg				
34	Manufactured	Tellow Tab. 80/10mg				
35	Manufactured	Tellow Tab. 80/20mg				
36	Manufactured	Tellow Tab. 80/5mg				

No.	Manufactured/ Imported	Product	Company	Date of Approval	Classification Code	Active Ingredient
37	Manufactured	Akarb Tablet 120/40mg	Boryung Pharmaceutical	2020-04-29	[219] Miscellaneous cardiovascular drugs	Fimasartan Potassium Trihydrate Granule, Atorvastatin Calcium Trihydrate
38	Manufactured	Akarb Tablet 30/10mg				
39	Manufactured	Akarb Tablet 30/20mg				
40	Manufactured	Akarb Tablet 60/10mg				
41	Manufactured	Akarb Tablet 60/20mg				
42	Manufactured	Hemoclean B solution (peracetic acid)	Huons Medicare Co., Ltd.	2020-05-25	[732] Disinfectants for quarantine	Peracetic Acid Solution
43	Manufactured	Rosuemzet Tab. 10/10mg	Mother's Pharmaceutical Co., Ltd.	2020-05-29	[218] Drugs for atherosclerosis	Rosuvastatin Calcium, Ezetimibe
44	Manufactured	Rosuemzet Tab. 10/20mg				
45	Manufactured	Rosuemzet Tab. 10/5mg				
46	Manufactured	Rosueze Tab. 10/10mg	MEDICA KOREA Co., Ltd.	2020-05-29	[218] Drugs for atherosclerosis	Rosuvastatin Calcium, Ezetimibe
47	Manufactured	Rosueze Tab. 10/20mg				
48	Manufactured	Rosueze Tab. 10/5mg				
49	Manufactured	ROSU DUO Tab. 10/10mg	Cires Pharmaceutical Inc.	2020-05-29	[218] Drugs for atherosclerosis	Rosuvastatin Calcium, Ezetimibe
50	Manufactured	ROSU DUO Tab. 10/20mg				
51	Manufactured	ROSU DUO Tab. 10/5mg				
52	Manufactured	Rotazet Tab. 10/10mg	Sinil Pharmaceutical Co., Ltd.	2020-05-29	[218] Drugs for atherosclerosis	Rosuvastatin Calcium, Ezetimibe
53	Manufactured	Rotazet Tab. 10/20mg				
54	Manufactured	Rotazet Tab. 10/5mg				
55	Manufactured	Rozetam Tab. 10/10mg	APROGEN Pharmaceuticals, Inc.	2020-05-29	[218] Drugs for atherosclerosis	Rosuvastatin Calcium, Ezetimibe
56	Manufactured	Rozetam Tab. 10/20mg				
57	Manufactured	Rozetam Tab. 10/5mg				
58	Manufactured	CVAZET Tab. 10/10mg	Wooridul Pharmaceutical Ltd.→ (name change)PharmGen Science Inc.	2020-05-29	[218] Drugs for atherosclerosis	Rosuvastatin Calcium, Ezetimibe
59	Manufactured	CVAZET Tab. 10/20mg				
60	Manufactured	CVAZET Tab. 10/5mg				

No.	Manufactured/ Imported	Product	Company	Date of Approval	Classification Code	Active Ingredient
61	Manufactured	Rovaeze Tab. 10/10mg	DongKoo Bio&Pharma Co., Ltd.	2020-06-23	[218] Drugs for atherosclerosis	Rosuvastatin Calcium, Ezetimibe
62	Manufactured	Rovaeze Tab. 10/20mg				
63	Manufactured	Rovaeze Tab. 10/5mg				
64	Manufactured	Rotibe Tab. 10/10mg	Binex Co., Ltd.	2020-06-23	[218] Drugs for atherosclerosis	Rosuvastatin Calcium, Ezetimibe
65	Manufactured	Rotibe Tab. 10/20mg				
66	Manufactured	Rotibe Tab. 10/5mg				
67	Manufactured	Rotizet Tab. 10/10mg	CMG Pharmaceutical Co., Ltd.	2020-06-23	[218] Drugs for atherosclerosis	Rosuvastatin Calcium, Ezetimibe
68	Manufactured	Rotizet Tab. 10/20mg				
69	Manufactured	Rotizet Tab. 10/5mg				
70	Manufactured	YUROVAZET Tablet 10/10mg	Yuyu pharma, Inc	2020-06-23	[218] Drugs for atherosclerosis	Rosuvastatin Calcium, Ezetimibe
71	Manufactured	YUROVAZET Tablet 10/20mg				
72	Manufactured	YUROVAZET Tablet 10/5mg				
73	Manufactured	Roze K Tab. 10/10mg	Kwangdong Pharm., Ltd.	2020-06-23	[218] Drugs for atherosclerosis	Rosuvastatin Calcium, Ezetimibe
74	Manufactured	Roze K Tab. 10/20mg				
75	Manufactured	Roze K Tab. 10/5mg				
76	Manufactured	Rovaduet Tab. 10/10mg	DAEWOOPHARM. CO., LTD.	2020-06-23	[218] Drugs for atherosclerosis	Rosuvastatin Calcium, Ezetimibe
77	Manufactured	Rovaduet Tab. 10/20mg				
78	Manufactured	Rovaduet Tab. 10/5mg				
79	Manufactured	ROEZE TAB. 10/10mg	DAEWOONG BIO Inc.	2020-06-23	[218] Drugs for atherosclerosis	Rosuvastatin Calcium, Ezetimibe
80	Manufactured	ROEZE TAB. 10/20mg				
81	Manufactured	ROEZE TAB. 10/5mg				
82	Manufactured	RZ Tab. 10/10mg	Dong Kwang Pharm. Co.,Ltd.	2020-06-23	[218] Drugs for atherosclerosis	Rosuvastatin Calcium, Ezetimibe
83	Manufactured	RZ Tab. 10/20mg				
84	Manufactured	RZ Tab. 10/5mg				

No.	Manufactured/ Imported	Product	Company	Date of Approval	Classification Code	Active Ingredient
85	Manufactured	Crevazet Tab. 10/10mg	Youngil Pharm. Co., Ltd.	2020-06-23	[218] Drugs for atherosclerosis	Rosuvastatin Calcium, Ezetimibe
86	Manufactured	Crevazet Tab. 10/20mg				
87	Manufactured	Crevazet Tab. 10/5mg				
88	Manufactured	Rosuvzet Tab. 10/10mg	JINYANG PHARM CO.,LTD.	2020-06-23	[218] Drugs for atherosclerosis	Rosuvastatin Calcium, Ezetimibe
89	Manufactured	Rosuvzet Tab. 10/20mg				
90	Manufactured	Rosuvzet Tab. 10/5mg				
91	Manufactured	Romizet Tablet 10/10mg	KOLON Pharma	2020-06-23	[218] Drugs for atherosclerosis	Rosuvastatin Calcium, Ezetimibe
92	Manufactured	Romizet Tablet 10/20mg				
93	Manufactured	Romizet Tablet 10/5mg				
94	Manufactured	Ezero Tab. 10/10mg	UNION KOREA PHARM	2020-06-23	[218] Drugs for atherosclerosis	Rosuvastatin Calcium, Ezetimibe
95	Manufactured	Ezero Tab. 10/20mg				
96	Manufactured	Ezero Tab. 10/5mg				
97	Manufactured	Rosuezet Tab. 10/10mg	Korea Prime Pharm. Co., Ltd.	2020-06-23	[218] Drugs for atherosclerosis	Rosuvastatin Calcium, Ezetimibe
98	Manufactured	Rosuezet Tab. 10/20mg				
99	Manufactured	Rosuezet Tab. 10/5mg				
100	Manufactured	Combiroze Tablet 10/10mg	Whan In Pharm. Co., Ltd.	2020-06-23	[218] Drugs for atherosclerosis	Rosuvastatin Calcium, Ezetimibe
101	Manufactured	Combiroze Tablet 10/20mg				
102	Manufactured	Combiroze Tablet 10/5mg				
103	Manufactured	Telotatin Tab. 40/5/10mg	UNIMED PHARM INC.	2020-06-30	[219] Miscellaneous cardiovascular drugs	Telmisartan, Rosuvastatin Calcium, Amlodipine Besylate
104	Manufactured	Telotatin Tab. 80/5/10mg				
105	Manufactured	EXONE-A Tab. 5/160/10mg	HK inno.N	2020-07-24	[219] Miscellaneous cardiovascular drugs	Atorvastatin Calcium Hydrate, Valsartan, Amlodipine Besylate
106	Manufactured	EXONE-A Tab. 5/160/20mg				
107	Manufactured	EXONE-A Tab. 5/80/10mg				
108	Manufactured	EXONE-A Tab. 5/80/20mg				

No.	Manufactured/ Imported	Product	Company	Date of Approval	Classification Code	Active Ingredient
109	Manufactured	Telmistin Tab. 40/10mg	GUJU PHARM.CO.,LTD.	2020-07-29	[219] Miscellaneous cardiovascular drugs	Telmisartan, Rosuvastatin Calcium
110	Manufactured	Telmistin Tab. 40/5mg				
111	Manufactured	Telmistin Tab. 80/10mg				
112	Manufactured	Telmistin Tab. 80/5mg				
113	Manufactured	TELOKE Tab. 40/10mg	Wooridul Pharmaceutical Ltd.→ (name change)PharmGen Science Inc.	2020-07-29	[219] Miscellaneous cardiovascular drugs	Telmisartan, Rosuvastatin Calcium
114	Manufactured	TELOKE Tab. 40/20mg				
115	Manufactured	TELOKE Tab. 40/5mg				
116	Manufactured	TELOKE Tab. 80/10mg				
117	Manufactured	TELOKE Tab. 80/20mg				
118	Manufactured	TELOKE Tab. 80/5mg				
119	Manufactured	Romitel Tablet 40/10mg	KOLON Pharma	2020-07-29	[219] Miscellaneous cardiovascular drugs	Telmisartan, Rosuvastatin Calcium
120	Manufactured	Romitel Tablet 40/20mg				
121	Manufactured	Romitel Tablet 40/5mg				
122	Manufactured	Romitel Tablet 80/10mg				
123	Manufactured	Romitel Tablet 80/20mg				
124	Manufactured	Romitel Tablet 80/5mg				
125	Manufactured	DUOTELMI TAB. 40/10mg	HUTECS KOREA PHARMACEUTICAL CO., LTD	2020-07-29	[219] Miscellaneous cardiovascular drugs	Telmisartan, Rosuvastatin Calcium
126	Manufactured	DUOTELMI TAB. 40/20mg				
127	Manufactured	DUOTELMI TAB. 40/5mg				
128	Manufactured	DUOTELMI TAB. 80/10mg				
129	Manufactured	DUOTELMI TAB. 80/20mg				
130	Manufactured	DUOTELMI TAB. 80/5mg				

No.	Manufactured/ Imported	Product	Company	Date of Approval	Classification Code	Active Ingredient
131	Manufactured	Avaltan A Plus Tab. 5/160/10mg	DongKoo Bio&Pharma Co., Ltd.	2020-09-25	[219] Miscellaneous cardiovascular drugs	Atorvastatin Calcium Hydrate, Valsartan, Amlodipine Besylate
132	Manufactured	Avaltan A Plus Tab. 5/160/20mg				
133	Manufactured	Avaltan A Plus Tab. 5/80/10mg				
134	Manufactured	Avaltan A Plus Tab. 5/80/20mg				
135	Manufactured	A.V.A-Tri Tab. 5/160/10mg	Daehan New Pharm Co., Ltd.	2020-09-25	[219] Miscellaneous cardiovascular drugs	Atorvastatin Calcium Hydrate, Valsartan, Amlodipine Besylate
136	Manufactured	A.V.A-Tri Tab. 5/160/20mg				
137	Manufactured	A.V.A-Tri Tab. 5/80/10mg				
138	Manufactured	A.V.A-Tri Tab. 5/80/20mg				
139	Manufactured	Valtrio Tab. 10/160/10mg	KyungDong pharm. co., Ltd	2020-09-29	[219] Miscellaneous cardiovascular drugs	Valsartan, Rosuvastatin Calcium, Amlodipine Besylate
140	Manufactured	Valtrio Tab. 10/160/20mg				
141	Manufactured	Valtrio Tab. 5/160/10mg				
142	Manufactured	Valtrio Tab. 5/80/10mg				
143	Manufactured	Omestar Soft Capsule	Penmix Ltd.	2020-10-12	[218] Drugs for atherosclerosis	Rosuvastatin Calcium, Omega-3-Acid Ethyl Esters 90
144	Manufactured	Lipilouzet Tab. 10/10mg	Chong Kun Dang Pharm.	2020-10-13	[218] Drugs for atherosclerosis	Rosuvastatin Calcium, Ezetimibe
145	Manufactured	Lipilouzet Tab. 10/20mg				
146	Manufactured	Lipilouzet Tab. 10/40mg				
147	Manufactured	AmosartanXQ Tab. 5/100/10/10 mg	Hanmi Pharm. Co., Ltd.	2020-11-09	[219] Miscellaneous cardiovascular drugs	Losartan Potassium, Ezetimibe, Rosuvastatin Calcium, Amlodipine Besylate
148	Manufactured	AmosartanXQ Tab. 5/100/20/10 mg				
149	Manufactured	AmosartanXQ Tab. 5/100/5/10 mg				
150	Manufactured	AmosartanXQ Tab. 5/50/10/10 mg				
151	Manufactured	AmosartanXQ Tab. 5/50/20/10 mg				
152	Manufactured	AmosartanXQ Tab. 5/50/5/10 mg				

No.	Manufactured/ Imported	Product	Company	Date of Approval	Classification Code	Active Ingredient
153	Manufactured	Cholestop Plus Tab. 10/5mg	White Life Science Co., Ltd.	2020-11-11	[218] Drugs for atherosclerosis	Rosuvastatin Calcium, Ezetimibe
154	Manufactured	Cholestop Plus Tab. 10/10mg				
155	Manufactured	Cholestop Plus Tab. 10/20mg				
156	Manufactured	Mega M Dual Soft Cap.	CMG Pharmaceutical Co., Ltd.	2020-12-01	[218] Drugs for atherosclerosis	Rosuvastatin Calcium, Omega-3-Acid Ethyl Esters 90
157	Manufactured	Megarovan Soft Cap. 5/1000mg	KyungDong pharm. co., Ltd	2020-12-01	[218] Drugs for atherosclerosis	Rosuvastatin Calcium, Omega-3-Acid Ethyl Esters 90
158	Manufactured	Totalsante Soft Capsule	Boryung Pharmaceutical	2020-12-01	[218] Drugs for atherosclerosis	Rosuvastatin Calcium, Omega-3-Acid Ethyl Esters 90
159	Manufactured	Rojecor Soft Capsule	Jeil Pharmaceutical Co., Ltd.	2020-12-01	[218] Drugs for atherosclerosis	Rosuvastatin Calcium, Omega-3-Acid Ethyl Esters 90
160	Manufactured	Romega Soft Capsule	GL Pharma	2020-12-01	[218] Drugs for atherosclerosis	Rosuvastatin Calcium, Omega-3-Acid Ethyl Esters 90
161	Manufactured	Rosuvaco Soft Cap.	Korea Prime Pharm. Co., Ltd.	2020-12-01	[218] Drugs for atherosclerosis	Rosuvastatin Calcium, Omega-3-Acid Ethyl Esters 90
162	Manufactured	ROSUCOMA SOFT CAP.	HUTECS KOREA PHARMACEUTICAL CO., LTD	2020-12-01	[218] Drugs for atherosclerosis	Rosuvastatin Calcium, Omega-3-Acid Ethyl Esters 90
163	Manufactured	Canderova Tab 10/16mg	Kyongbo pharma	2020-12-11	[219] Miscellaneous cardiovascular drugs	Candesartan Cilexetil, Amlodipine Besylate
164	Manufactured	Canderova Tab 10/8mg				
165	Manufactured	Canderova Tab 20/32mg				
166	Manufactured	Canderova Tab 5/16mg				
167	Manufactured	Canderova Tab 5/8mg				
168	Manufactured	CantacanDuo Tab.10/16mg	Celltrion Pharm, Inc.	2020-12-11	[219] Miscellaneous cardiovascular drugs	Candesartan Cilexetil, Rosuvastatin Calcium
169	Manufactured	CantacanDuo Tab.10/8mg				
170	Manufactured	CantacanDuo Tab.20/32mg				
171	Manufactured	CantacanDuo Tab.5/16mg				
172	Manufactured	CantacanDuo Tab.5/8mg				

No.	Manufactured/ Imported	Product	Company	Date of Approval	Classification Code	Active Ingredient
173	Manufactured	CRECANDE TAB. 10/16mg	HUTECS KOREA PHARMACEUTICAL CO., LTD	2020-12-11	[219] Miscellaneous cardiovascular drugs	Candesartan Cilexetil, Rosuvastatin Calcium
174	Manufactured	CRECANDE TAB. 10/8mg				
175	Manufactured	CRECANDE TAB. 20/32mg				
176	Manufactured	CRECANDE TAB. 5/16mg				
177	Manufactured	CRECANDE TAB. 5/8mg				
178	Imported	Atectura Inhalation capsule 150/160 micrograms	Novartis Korea	2020-12-24	[229] Miscellaneous respiratory organ drugs	Mometasone Furoate, Indacaterol Acetate
179	Imported	Atectura Inhalation capsule 150/320 micrograms				
180	Imported	Atectura Inhalation capsule 150/80 micrograms				
181	Imported	Enerzair Inhalation capsule 150/50/160 micrograms				Mometasone Furoate, Indacaterol Acetate, Glycopyrronium Bromide
182	Imported	Enerzair Inhalation capsule 150/50/80 micrograms				

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

Table 34. Approval Status of Drugs with Changes in Strength of Active Substances that Require Data Submission in 2020

No.	Manufactured / Imported	Product	Company	Date of Approval	Classification Code	Efficacy/Effectiveness (partially summarized)
1	Manufactured	Masibone S Sol. (Sodium alendronate hydrate)	DongKook Pharmaceutical Co., Ltd.	2020-03-31	[399]Miscellaneous metabolic drugs	Treatment of osteoporosis
2	Manufactured	Amodipin Tab. 2.5mg (Amlodipine camsylate)	Hanmi Pharm. Co., Ltd.	2020-03-31	[214] Antihypertensives	Hypertension, myocardial ischemia, etc.
3	Manufactured	Uropa SR Tab. 0.4mg (Tamsulosin HCl)	Dongkoo Bio&Pharma Co., Ltd.	2020-04-17	[259] Miscellaneous urogenital and anal organ drugs	Urinary disorder due to positive prostate hyperplasia
4	Manufactured	Binex Tamsulosin HCl SR Tab. 0.4mg	Binex Co., Ltd.	2020-04-17	[259] Miscellaneous urogenital and anal organ drugs	Urinary disorder due to positive prostate hyperplasia
5	Manufactured	Tamsgreen SR Tab. 0.4mg (Tamsulosin HCl)	Cires Pharmaceutical Inc.	2020-04-17	[259] Miscellaneous urogenital and anal organ drugs	Urinary disorder due to positive prostate hyperplasia
6	Manufactured	Tamspro SR Tablet 0.4mg (Tamsulosin HCl)	Pharvis Korea Pharm Co., Ltd.	2020-04-17	[259] Miscellaneous urogenital and anal organ drugs	Urinary disorder due to positive prostate hyperplasia
7	Manufactured	Ulosin SR Tab. 0.4mg (Tamsulosin HCl)	White Life Science Co., Ltd.	2020-04-17	[259] Miscellaneous urogenital and anal organ drugs	Urinary disorder due to positive prostate hyperplasia
8	Manufactured	Tamsulosin SR Tab. 0.4mg (Tamsulosin HCl)	Daewoo Pharm Co., Ltd.	2020-04-17	[259] Miscellaneous urogenital and anal organ drugs	Urinary disorder due to positive prostate hyperplasia
9	Manufactured	Tarosin SR Tab. 0.4mg (Tamsulosin HCl)	Daehan New Pharm co.,Ltd.	2020-04-17	[259] Miscellaneous urogenital and anal organ drugs	Urinary disorder due to positive prostate hyperplasia
10	Manufactured	SAMSUNG Tamsulosin SR Tab 0.4mg (Tamsulosin HCl)	SAMSUNG PHARM Co., Ltd.	2020-04-17	[259] Miscellaneous urogenital and anal organ drugs	Urinary disorder due to positive prostate hyperplasia
11	Manufactured	Tamszin SR Tab. 0.4mg (Tamsulosin HCl)	ICURE Pharmaceutical Inc.	2020-04-17	[259] Miscellaneous urogenital and anal organ drugs	Urinary disorder due to positive prostate hyperplasia
12	Manufactured	Lutsnal SR Tablet 0.4mg (Tamsulosin HCl)	Alvogen Korea Co., Ltd.	2020-04-17	[259] Miscellaneous urogenital and anal organ drugs	Urinary disorder due to positive prostate hyperplasia

No.	Manufactured / Imported	Product	Company	Date of Approval	Classification Code	Efficacy/Effectiveness (partially summarized)
13	Manufactured	Tamsulosin SR Tab. 0.4mg (Tamsulosin HCl)	APROGEN Pharmaceuticals, Inc.	2020-04-17	[259] Miscellaneous urogenital and anal organ drugs	Urinary disorder due to positive prostate hyperplasia
14	Manufactured	PRATAM SR Tab. 0.4mg (Tamsulosin HCl)	Wooridul Pharmaceutical Ltd.→ (name change)PharmGen Science Inc.	2020-04-17	[259] Miscellaneous urogenital and anal organ drugs	Urinary disorder due to positive prostate hyperplasia
15	Manufactured	Qminal SR Tab. 0.4mg (Tamsulocin Hydrochloride)	QI Pharma Co., Ltd.	2020-04-17	[259] Miscellaneous urogenital and anal organ drugs	Urinary disorder due to positive prostate hyperplasia
16	Manufactured	Tamsable ER Tablet 0.4mg (Tamsulosin HCl)	KMS Pharm Co., Ltd.	2020-04-17	[259] Miscellaneous urogenital and anal organ drugs	Urinary disorder due to positive prostate hyperplasia
17	Manufactured	Tamsulo SR Tab. 0.4mg (tamsulosin hydrochloride)	KOLON Pharma	2020-04-17	[259] Miscellaneous urogenital and anal organ drugs	Urinary disorder due to positive prostate hyperplasia
18	Manufactured	TAMSTRO SR Tab. 0.4mg (Tamsulosin HCl)	Korea United Pharm. Inc.	2020-04-17	[259] Miscellaneous urogenital and anal organ drugs	Urinary disorder due to positive prostate hyperplasia
19	Manufactured	Boryung Tamsulosin SR Tablet 0.4mg	Boryung Pharmaceutical	2020-04-29	[259] Miscellaneous urogenital and anal organ drugs	Urinary disorder due to positive prostate hyperplasia
20	Manufactured	KwangDong Liver Shot Tablets 300	Kwangdong Pharm., Ltd.	2020-06-19	[329] Miscellaneous nourishing nutrients, tonic and alternatives	Nutrient supplementation, nourishing tonic
21	Manufactured	Neustazet-R Tablet 10/10mg	Samjin Pharmaceuti-cal Co., Ltd.	2020-06-23	[218] Drugs for atherosclerosis	Hypercholesterolemia
22	Manufactured	THIODAN Tab. 32.5mg (potassium iodide)	Korea United Pharm. Inc.	2020-07-02	[322] Mineral preparations	Thyroid protection in the event of a radiation crisis
23	Manufactured	IRcodonTab. 20mg (Oxycodone hydrochloride)	UNIMED PHARM INC.	2020-08-21	[821] Synthetic opioids	Narcotic analgesics
24	Manufactured	Myoguard Eye Drops 0.125% (Atropine Sulfate) (Unit Dose))	LitePharmTech	2020-11-02	[131] Ophthalmic drugs	Diagnosis and treatment for mydriasis
25	Imported	ASACOL DR TAB 1600mg (Mesalazine)	DAEWOONG PHARMACE-UTICAL CO.,LTD.	2020-11-17	[239] Miscellaneous digestive organ drugs	Treatment and maintenance of mild and moderate active ulcerative colitis

No.	Manufactured / Imported	Product	Company	Date of Approval	Classification Code	Efficacy/Effectiveness (partially summarized)
26	Imported	Cyclogest 400mg	Zanovex Korea Co., Ltd.	2020-11-25	[247] Follicle hormone drugs and corpora lutea hormone drugs	Replacement therapy for luteal phase, as a part of female assisted reproductive technology

4) Drugs with new mode of administration/dose (3 items)

3 items (1 manufactured item, 2 imported items) were chemical drugs approved with a new mode of administration/dose. These include a drug developed through convergence with a medical device (collagen absorbent wound dressing, etc.) whose active ingredient is thrombin, and a nasal spray whose active ingredient is fentanyl citrate. For the nasal spray, the maximum dose was increased from that of the previously approved (notified) fentanyl citrate nasal spray (400 → 800 micrograms) (Refer to Table 35).

Table 35. Approval Status of Drugs with New Dosage/Mode of Administration that Require Data Submission in 2020

No.	Manufactured/ Imported	Product	Company	Date of Approval	Classification Code	Efficacy/ Effectiveness (partially summarized)
1	Manufactured	Stopi Hemostatic	BMI Korea Co., Ltd.	2020-11-19	[332] Hemostatics	Hemostasis
2	Imported	Pecfent Nasal Spray 100 μg (fentanyl citrate)	Menarini Korea Ltd.	2020-01-09	[821] Synthetic opioids	Breakthrough pain in cancer patients who have tolerance to narcotic analgesics
3	Imported	Pecfent Nasal Spray 400 μg (fentanyl citrate)	Menarini Korea Ltd.	2020-01-09	[821] Synthetic opioids	

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

5) Drugs with a new dosage form (same route of administration) (39 items)

Chemical drugs approved with a new dosage form (same route of administration) included 39 items (36 manufactured items and 3

imported items). The approved types of dosage form development are as follows: 27 items (69.2%) developed from existing immediate-release drugs (tablets or capsules) into extended-release drugs (tablets or capsules), 5 items (12.8%) developed from tablets into capsules or from capsules into tablets, 1 item developed from an existing patch into a gel, an item developed from a spray into a gargle, 1 item developed from a chewable tablet into a tablet, and 1 item developed from a tablet into an orodispersible film (Refer to Table 36).

Table 36. Approval Status of Drugs with New Dosage Form (Same Route of Administration) that Require Data Submission in 2020

No.	Manufactured/ Imported	Product	Company	Date of Approval	Classification Code	Efficacy/Effectiveness (Partially summarized)	New Dosage Form
1	Manufactured	LOXO-N GEL (Loxoprofen Sodium Hydrate)	DONGSUNG BIO PHARM. CO., LTD.	2020-02-17	[264] Drugs for pain-relieving, antipruritic, convergence, anti-inflammatory	Arthralgia, myalgia, etc.	Patch → Gel
2	Manufactured	Allopanten Tablets 100mg (Dexpanthenol)	Kolmar Pharma Co., Ltd.	2020-02-21	[267] Agents for hair (hair grower, hair loss treatment, hair dye, and hair tonic)	Adjuvant treatment for hair loss	Ointment and others → tablet
3	Manufactured	Withfull Cap.	INTRO BIO PHARMA	2020-03-19	[399]Miscellaneous metabolic drugs	Adjuvant therapy for weight loss	Tablet → Capsule
4	Manufactured	Renexin CR tab	SK Chemicals	2020-03-24	[339]Miscellaneous blood and body fluid drugs	Improvement of ischemic symptoms, such as ulcers, pain, coldness and others due to chronic arterial occlusion	Tablet → ER tablet
5	Manufactured	Riroxia Cap. 2.5mg (Rivaroxaban)	Chong Kun Dang Pharm.	2020-04-09	[333] Anticoagulants	Anticoagulants	Tablet → Capsule
6	Manufactured	Dilatrend SR Tab. 16mg (Carvedilol)	Chong Kun Dang Pharm.	2020-04-16	[214] Anti-hypertensives	Treatment of hypertension and others	Capsule → Tablet
7	Manufactured	Dilatrend SR Tab. 8mg (Carvedilol)	Chong Kun Dang Pharm.	2020-04-16	[214] Anti-hypertensives	Treatment of hypertension and others	Capsule → Tablet

No.	Manufactured/ Imported	Product	Company	Date of Approval	Classification Code	Efficacy/Effectiveness (Partially summarized)	New Dosage Form
8	Manufactured	Tamsuall SR Tab. 0.4mg (Tamsulosin HCl)	Dasan Pharmaceutical Co., Ltd.	2020-04-24	[259] Miscellaneous urogenital and anal organ drugs	Urinary disorder due to positive prostate hyperplasia	Capsule → SR tablet
9	Manufactured	Tamscare ER 0.4mg (Tamsulosin Hydrochloride)	LitePharmTech	2020-04-24	[259] Miscellaneous urogenital and anal organ drugs	Urinary disorder due to positive prostate hyperplasia	Capsule → ER tablet
10	Manufactured	C-trosin SR Tab. 0.4mg (Tamsulosin HCl)	HLB PHARMACEUTICAL CO., LTD.	2020-04-24	[259] Miscellaneous urogenital and anal organ drugs	Urinary disorder due to positive prostate hyperplasia	Capsule → ER tablet
11	Manufactured	Day Tams SR Tab. 0.4mg (Tamsulosin Hydrochloride)	Boryung Biopharma Co., Ltd.	2020-04-24	[259] Miscellaneous urogenital and anal organ drugs	Urinary disorder due to positive prostate hyperplasia	Capsule → ER tablet
12	Manufactured	Tamsol SR Tab. 0.4mg (Tamsulosin HCl)	Celltrion Pharm	2020-04-24	[259] Miscellaneous urogenital and anal organ drugs	Urinary disorder due to positive prostate hyperplasia	Capsule → ER tablet
13	Manufactured	Tamslon SR Tab. 0.4mg (Tamsulosin HCl)	AUSKOREA PHARM CO., LTD.	2020-04-24	[259] Miscellaneous urogenital and anal organ drugs	Urinary disorder due to positive prostate hyperplasia	Capsule → ER tablet
14	Manufactured	Tamunal SR Tab 0.4mg (Tamsulosin HCl)	Chong Kun Dang Pharm.	2020-04-24	[259] Miscellaneous urogenital and anal organ drugs	Urinary disorder due to positive prostate hyperplasia	Capsule → ER tablet
15	Manufactured	Tamstar SR tab. (Tamsulosin hydrochloride)	Pharmbio Korea Inc.	2020-04-24	[259] Miscellaneous urogenital and anal organ drugs	Urinary disorder due to positive prostate hyperplasia	Capsule → ER tablet
16	Manufactured	Tamlusin D SR Tablet 0.4mg (Tamsulosin HCl)	Huons Co., Ltd.	2020-04-24	[259] Miscellaneous urogenital and anal organ drugs	Urinary disorder due to positive prostate hyperplasia	Capsule → ER tablet
17	Manufactured	Uronal SR Tab. 0.4mg (Tamsulosin HCl)	KyungDong pharm. co., Ltd	2020-04-24	[259] Miscellaneous urogenital and anal organ drugs	Urinary disorder due to positive prostate hyperplasia	Capsule → ER tablet
18	Manufactured	Tamsronal SR Tab. 0.4mg (Tamsulosin HCl)	GUJU PHARM.CO., LTD.	2020-04-24	[259] Miscellaneous urogenital and anal organ drugs	Urinary disorder due to positive prostate hyperplasia	Capsule → ER tablet
19	Manufactured	BEAROSIN SR TAB. 0.4 mg (Tamsulosin Hydrochloride)	Daewoong Bio Inc.	2020-04-24	[259] Miscellaneous urogenital and anal organ drugs	Urinary disorder due to positive prostate hyperplasia	Capsule → ER tablet

No.	Manufactured/ Imported	Product	Company	Date of Approval	Classification Code	Efficacy/Effectiveness (Partially summarized)	New Dosage Form
20	Manufactured	DongKwang TAMSULOSIN SR Tab. 0.4mg (Tamsulosin HCl)	Dong Kwang Pharm. Co.,Ltd.	2020-04-24	[259] Miscellaneous urogenital and anal organ drugs	Urinary disorder due to positive prostate hyperplasia	Capsule → ER tablet
21	Manufactured	HARUSIN SR TABLET 0.4mg (Tamsulosin Hydrochloride)	AJU PHARM CO., LTD.	2020-04-24	[259] Miscellaneous urogenital and anal organ drugs	Urinary disorder due to positive prostate hyperplasia	Capsule → ER tablet
22	Manufactured	Harucure Cap. (Tamsulosin hydrochloride)	Ahngook Pharm.	2020-04-24	[259] Miscellaneous urogenital and anal organ drugs	Urinary disorder due to positive prostate hyperplasia	Capsule → ER tablet
23	Manufactured	Arlunal SR Tab. 0.4mg (Tamsulosin Hydrochloride)	Korea Arlico Pharm Co., Ltd.	2020-04-24	[259] Miscellaneous urogenital and anal organ drugs	Urinary disorder due to positive prostate hyperplasia	Capsule → ER tablet
24	Manufactured	Tamslen SR tab. 0.4mg (Tamsulosin HCl)	Neo Bio Korea Pharm. Co., Ltd.	2020-04-24	[259] Miscellaneous urogenital and anal organ drugs	Urinary disorder due to positive prostate hyperplasia	Capsule → ER tablet
25	Manufactured	Tamrosin SR Tab. 0.4mg (Tamsulosin HCl)	Yungjin Pharm.	2020-04-24	[259] Miscellaneous urogenital and anal organ drugs	Urinary disorder due to positive prostate hyperplasia	Capsule → ER tablet
26	Manufactured	Tams tab 0.4mg (Tamsulosin HCl)	Young Poong Pharmaceutical Co.,Ltd.	2020-04-24	[259] Miscellaneous urogenital and anal organ drugs	Urinary disorder due to positive prostate hyperplasia	Capsule → ER tablet
27	Manufactured	DOUBLETAMS SR TAB. 0.4mg (Tamsulosin Hydrochloride)	VIVOZON PHARMACEUTICAL CO., LTD.	2020-04-24	[259] Miscellaneous urogenital and anal organ drugs	Urinary disorder due to positive prostate hyperplasia	Capsule → ER tablet
28	Manufactured	Tamsicare (Tamsulosin Hydrochloride)	THEU	2020-04-24	[259] Miscellaneous urogenital and anal organ drugs	Urinary disorder due to positive prostate hyperplasia	Capsule → ER tablet
29	Manufactured	Harutam SR Tab. 0.4mg (Tamsulosin HCl)	Hana pharm	2020-04-24	[259] Miscellaneous urogenital and anal organ drugs	Urinary disorder due to positive prostate hyperplasia	Capsule → ER tablet
30	Imported	Fycompa Oral Suspension 0.5mg/ml (Perampanel)	Eisai Korea	2020-05-28	[113] Antiepileptics	Treatment of partial seizure, etc.	Tablet → Suspension
31	Imported	Children's Tylenol Powder 160mg (Acetaminophen)	Johnson & Johnson Korea	2020-08-03	[114] Antipyretics, analgesics, and anti-inflammatory drugs	Fever and pain from a cold, headache, neuralgia, myalgia, menstrual pain, sprain pain, etc.	Tablet → Powder
32	Manufactured	Esomezol DR Cap. 20mg (Esomeprazole magnesium trihydrate)	Hanmi Pharm. Co., Ltd.	2020-10-06	[232] Peptic ulcer agents	Gastroesophageal reflux disease	Tablet → ER capsule

No.	Manufactured/ Imported	Product	Company	Date of Approval	Classification Code	Efficacy/Effectiveness (Partially summarized)	New Dosage Form
33	Manufactured	Esomezol DR Cap. 40mg (Esomeprazole magnesium trihydrate)	Hanmi Pharm. Co., Ltd.	2020-10-06	[232] Peptic ulcer agents	Gastroesophageal reflux disease	Tablet → ER capsule
34	Manufactured	ORASENSE Liquid (flurbiprofen) ORASENSE Liquid peppermint (flurbiprofen)	DongKook Pharmaceutical Co., Ltd.	2020-10-15	[231] Dental and oral drugs	Oropharyngeal inflammation such as stomatitis, gingivitis, pharyngitis, etc.	Spray, etc → Gargle
35	Manufactured	MUCONA INJECTION (Acetylcysteine) (Vial)	AJU PHARM CO., LTD.	2020-10-26	[222] Antitussive expectorants	Antitussive expectorants	Ampoule → Vial
36	Imported	XELJANZ® XR Extended-Release Tablets (tofacitinib citrate)	Pfizer Korea	2020-12-07	[142] Non-specific immunogen preparations	Rheumatoid arthritis	Tablet → SR tablet
37	Manufactured	nosefree soft cap.	RP Bio Inc.	2020-12-11	[141] Antihistamines	Alleviation of following symptoms due to head cold, allergy and vasomotor rhinitis	Tablet → Soft capsule
38	Manufactured	Perrier Tab.	Intropharm Inc.	2020-12-15	[234] Antacids	Hyperacidity and heartburn	Chewable tablet → tablet
39	Manufactured	GCWB Selenium Oral Dissolving Film (Sodium selenite pentahydrate)	GC Wellbeing	2020-12-31	[322] Mineral preparations	Provision of selenium	Tablet, etc. → Oro-dispersible film

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

3

Approval Status of Biopharmaceuticals

3. Approval Status of Biopharmaceuticals

According to an analysis of biopharmaceuticals approved in 2020 based on regulatory review pathways, there were 5 new drugs (excluding new drugs removed from the orphan drug list, etc.), 38 drugs requiring data submission (34 other drugs requiring data submission) and 10 orphan drugs (excluding four new orphan drugs) (Refer to Table 37). More specifically, 20 biologics and 33 recombinant protein products were approved (Refer to Table 38).

Table 37. Approval Status of Biopharmaceuticals by Review Type in 2020

<Including Drugs for Export Only and Active Pharmaceutical Ingredients>

<table>
<tr><th>Type</th><th colspan="3">Review Type</th><th>No. of Approved Items</th></tr>
<tr><td>1</td><td rowspan="2">New drugs (5)</td><td colspan="2">New drugs</td><td>1</td></tr>
<tr><td>2</td><td>New orphan drugs</td><td rowspan="2">Orphan drugs (14)</td><td>4</td></tr>
<tr><td>3</td><td colspan="2">Orphan drugs</td><td>10</td></tr>
<tr><td>4</td><td colspan="3">Drugs requiring data submission</td><td>38</td></tr>
<tr><td>4-1</td><td colspan="3">Incrementally modified drugs</td><td>0</td></tr>
<tr><td>4-2</td><td rowspan="2">Drugs requiring data submission</td><td colspan="2">Biosimilar products</td><td>4</td></tr>
<tr><td>4-3</td><td colspan="2">Other drugs requiring data submission</td><td>34</td></tr>
<tr><td>5</td><td colspan="3">Cell therapy products</td><td>0</td></tr>
<tr><td colspan="4">Total</td><td>53</td></tr>
</table>

<Excluding Drugs for Export Only and Active Pharmaceutical Ingredients>

<table>
<tr><th>Type</th><th colspan="3">Review Type</th><th>No. of Approved Items</th></tr>
<tr><td>1</td><td rowspan="2">New drugs (5)</td><td colspan="2">New drugs</td><td>1</td></tr>
<tr><td>2</td><td>New orphan drugs</td><td rowspan="2">Orphan drugs (14)</td><td>4</td></tr>
<tr><td>3</td><td colspan="2">Orphan drugs</td><td>10</td></tr>
<tr><td>4</td><td colspan="3">Drugs requiring data submission</td><td>22</td></tr>
<tr><td>4-1</td><td colspan="3">Incrementally modified drugs</td><td>0</td></tr>
<tr><td>4-2</td><td rowspan="2">Drugs requiring data submission</td><td colspan="2">Biosimilar products</td><td>4</td></tr>
<tr><td>4-3</td><td colspan="2">Other drugs requiring data submission</td><td>18</td></tr>
<tr><td>5</td><td colspan="3">Cell therapy products</td><td>0</td></tr>
<tr><td colspan="4">Total</td><td>37</td></tr>
</table>

Table 38. Approval Status of Biopharmaceuticals in 2020

<Including Drugs for Export Only and Active Pharmaceutical Ingredients>

Type	Total	No. of Approved Items		Remarks
		Manufactured	Imported	
Total	53	24	29	
Biologics	20	18	2	Drugs requiring data submission (20, including drugs for export (11), active pharmaceutical ingredient (1))
Recombinant Protein Products	33	6	27	New drugs (5), Orphan (10, excluding new orphan drug), drugs requiring data submission (18, including drugs for export(3), active pharmaceutical ingredient(1))
Cell therapy products	0	0	0	-
Gene therapy products	0	0	0	-
Others	0	0	0	-

<Excluding Drugs for Export Only and Active Pharmaceutical Ingredients>

Type	Total	No. of Approved Items		Remarks
		Manufactured	Imported	
Total	37	8	29	
Biologics	8	6	2	Drugs requiring data submission (8)
Recombinant Protein Products	29	2	27	New drugs (5), Orphan (10, excluding new orphan drug), Drugs requiring data submission (14)
Cell therapy products	0	0	0	-
Gene therapy products	0	0	0	-
Others	0	0	0	-

3.1. Approval Status of Biologics

In 2020, 20 biologics were approved (18 manufactured items / 2 imported items / 9 vaccines, 7 botulinum toxins, and 4 blood products). 6 items (6 manufactured items / 4 vaccines, and 2 botulinum toxins) were approved in 2019, 11 items (8 manufactured items, 3 imported items/ 9 vaccines, 1 botulinum toxin and 1 blood product) were approved in 2018, and 12 items (11 manufactured items, 1 imported item / 8 vaccines, 2 botulinum toxins, 2 blood products) were approved in 2017. The item approval of biopharmaceuticals tended to decrease after 2017, but increased again in 2020.

Vaccines approved in 2020 include 4 influenza vaccines, 1 varicella vaccine, 1 hepatitis A vaccine, 1 polio vaccine, 1 pneumonia vaccine, and 1 combined vaccine (Refer to Table 39).

In the case of influenza vaccines, vaccine production with strains suggested by the World Health Organization (WHO) every year is recommended, and they are classified as chicken egg vaccines and cell culture vaccines depending on the manufacturing processes.

Influenza vaccines approved in 2020 included 2 items for domestic use [Afluria QUAD PFS and Boryung FluXI Tetra Vaccine PFS by Boryung Biopharma], and 2 items for export [SKYcellflu Quadrivalent Prefilled Syringe (for export) and SKYcellflu Prefilled Syringe (for export) by SK Bioscience].

A domestically approved item **“Boryung FluXI Tetra Vaccine PFS”** by Boryung Biopharma and an imported item **“Afluria QUAD PFS”** were approved for the prevention of influenza disease caused by influenza A and B viruses contained in those vaccines in children 5 years of age or older, adolescents and adults.1

"SKYcellflu Quadrivalent Prefilled Syringe (for export)" and "SKYcell flu Prefilled Syringe (for export)" by SK Bioscience were approved for export.

For the varicella vaccine, "BARYCELA Inj." by Green Cross was approved for the prevention of varicella in children aged between 12 months to 12. For the hepatitis A vaccine, "Boryung Hepatitis A Vaccine PFS(Absobed, Inactivated)" by Boryung Biopharma was approved for the prevention of hepatitis A virus in children from 12 months to 2 years of age and adolescents 16 years of age or older and adults

"Eupolio Inj. (for export)" by LG Chem was approved as a polio vaccine, and "Skypheumo Prefilled Syringe (for export)" by SK Bioscience was approved as a pneumonia vaccine.

For combination vaccines approved in 2020, "Hexaxim Prefilled Syringe Inj." by Sanofi Pasteur was approved for the prevention of diphtheria, tetanus, pertussis, hepatitis B and polio (poliomyelitis) as well as invasive diseases caused by haemophilus influenzae type b (Hib) in infants 2 months of age or older.

In the case of botulinum toxin products, 4 items in 2016, 2 items in 2017, 1 item in 2018, and 2 items (1 for domestic use and the other for export only) in 2019, and 7 items in 2020 were approved as new drugs (Refer to Table 39).

Among the botulinum toxins approved in 2020, 2 items are "BTSA9(Clostrium botulinum toxin type A)" by Protox, and "Toxnine Inj. 100 Unit (for export)" by Medica Korea. These products have

been approved for temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activities in adults aged between 18 and 65.

Other botulinum toxins approved in 2020 include 5 items: **“Hitox Inj. 100 Unit (for export)”** by BMI Korea, **“BIENOX Injection (for export)”** by BNC Korea, **“Jetema The Toxin Inj. 100U (for export)”** by Jetema, **“INIBO Inj. 100 Units (for export)”** by Inibio, and **“ReNTox Inj. 200 Units (for export)”** by Pharma Research Bio. These products have also been approved for temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activities in adults aged between 19 and 65.

In the case of blood products, 4 items were approved in 2020, whereas the number of newly approved items was two in 2017, one in 2018, and none in 2019 (Refer to Table 39).

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 MFDS will continue to provide technical support to increase the nation’s self-sufficiency in essential preventive vaccines and core vaccines.

Table 39. List of Approved Biologics in 2020

No.	Manufactured / Imported	Product	Ingredient	Company	Date of Approval	Efficacy/Effectiveness (Partially summarized)	Remarks
1	Manufactured	BARYCELA inj. (Live Attenuated Varicella Vaccine)	Live Attenuated Varicella Vaccine	GC Pharma	2020-03-02	Prevention of varicella in children 12 months to 12 years of age	Drugs requiring data submission
2	Manufactured	Platelets, Pheresis, Leukocyte-depleted and Washed (W-PLT)	Washed platelet	Korean Red Cross Seoul Central Blood Laboratory Center	2020-03-05	1. Prevention or treatment of bleeding in patients with thrombocytopenia or platelet dysfunction 2. Patients with a history of transfusion side effects caused by plasma proteins after transfusion such reactions, anaphylaxis, etc.as urticaria, allergic	Drugs requiring data submission
3	Manufactured	Platelets, Pheresis, Leukocyte-depleted and Washed (W-PLT)	Washed platelet	Korean Red Cross Seoul Dongbu blood Center	2020-03-05	1. Prevention or treatment of bleeding in patients with thrombocytopenia or platelet dysfunction 2. Patients with a history of transfusion side effects caused by plasma proteins after transfusion such as urticaria, allergic reactions, anaphylaxis, etc.	Drugs requiring data submission
4	Manufactured	Platelets, Pheresis, Leukocyte-depleted and Washed (W-PLT)	Washed platelet	Korean Red Cross Gwangju·Jeonnam Blood Center	2020-03-05	1. Prevention or treatment of bleeding in patients with thrombocytopenia or platelet dysfunction 2. Patients with a history of transfusion side effects caused by plasma proteins after transfusion such as urticaria, allergic reactions, anaphylaxis, etc.	Drugs requiring data submission
5	Imported	Afluria QUAD PFS (Split Virion, Inactivated)	Purified inactivated influenza virus surface antigen type A, and purified inactivated influenza virus surface antigen type B	Boryung Biopharma Co., Ltd.	2020-03-16	Prevention of influenza diseases caused by influenza A and B viruses contained in this vaccine in children 5 years of age or older, adolescents and adults	Drugs requiring data submission
6	Imported	Hexaxim Prefilled Syringe Inj. (Diphtheria, tetanus, pertussis (acellular,compone-nt), poliomyelitis (inactivated),haem	Haemophilus influenza type B polysaccharide conjugated to diphtheria toxoid, pertussis toxoid,	Sanofi Pasteur	2020-04-14	Prevention of diphtheria, tetanus, pertussis, hepatitis B and polio (poliomyelitis) as well as invasive diseases caused by haemophilus	Drugs requiring data submission

No.	Manufactured / Imported	Product	Ingredient	Company	Date of Approval	Efficacy/Effectiveness (Partially summarized)	Remarks
		ophilus influenzae type b conjugate and hepatitis B (rDNA)combination vaccine)	filament hemagglutinin, inactivated polio virus, purified hepatitis B surface antigen protein, and tetanus toxoid			influenzae type b (Hib) in infants 2 months of age or older	
7	Manufactured	Boryung FluXI Tetra Vaccine PFS (Split Virion, Inactivated)	Purified inactivated influenza virus surface antigen type A, and purified inactivated influenza virus surface antigen type B	Boryung Biopharma Co., Ltd.	2020-10-29	Prevention of influenza diseases caused by influenza A and B viruses contained in this vaccine in children 5 years of age or older, adolescents and adults	Drugs requiring data submission
8	Manufactured	Boryung Hepatitis A Vaccine PFS (Adsorbed, Inactivated)	Inactivated hepatitis A virus antigen	Boryung Biopharma Co., Ltd.	2020-12-29	Prevention of disease caused by hepatitis A virus in children from 12 months to 2 years of age and adolescents 16 years of age or older and adults	Drugs requiring data submission
9	Manufactured	SK Human Tetanus Immunoglobulin Final Bulk	Anti-tetanus human immunoglobulin	SK Plasma Co., Ltd.	2020-02-18	For manufacturing of anti-tetanus human immunoglobulin	Stock solution
10	Manufactured	SKYCellflu Quadrivalent Prefilled syringe (surface antigen, inactivated, prepared in cell cultures) (for export)	Purified inactivated influenza virus surface antigen type A, and purified inactivated influenza virus surface antigen type B	SK Bioscience Co.,Ltd.	2020-01-09	Prevention of influenza diseases caused by influenza A and B viruses contained in this vaccine in children 6 months of age or older, adolescents and adults	For export
11	Manufactured	SKYCellflu Prefilled syringe (surface antigen, inactivated, prepared in cell cultures) (for export)	Purified inactivated influenza virus surface antigen type A, and purified inactivated influenza virus surface antigen type B	SK Bioscience Co.,Ltd.	2020-01-10	Prevention of influenza diseases caused by influenza A and B viruses contained in this vaccine in children 6 months of age or older, adolescents and adults	For export
12	Manufactured	BIENOX Injection (Clostridium Botulinum Toxin Type A) (for export)	Clostridium Botulinum Toxin Type A	BNC KOREA, LTD.	2020-01-13	Temporary improve-ment of moderate to severe glabellar lines associated with corrugator muscle and/or procerus	For export

No.	Manufactured / Imported	Product	Ingredient	Company	Date of Approval	Efficacy/Effectiveness (Partially summarized)	Remarks
						muscle activity in adults aged between 19 and 65	
13	Manufactured	Hitox Inj. 100Unit (Clostridium Botulinum Toxin Type A) (for export)	Clostridium Botulinum Toxin Type A	BNC KOREA, LTD.	2020-01-13	Temporary improvement of moderate to severe glabellar lines associated with corrugator muscle and/or procerus muscle activity in adults aged between 19 and 65	For export
14	Manufactured	Eupolio Inj. (Inactivated polio vaccine (Sabin Inj.)) (for export)	Inactivated polio virus	LG Chem Ltd.	2020-04-02	Prevention of polio in children 6 months years of age or older	For export
15	Manufactured	SKYPneumo Prefilled syringe (for export)	Purified pneumococcal polysaccharide - diphtheria CRM protein conjugate	SK Bioscience Co.,Ltd.	2020-05-14	1. Prevention of following diseases in infants aged 6 weeks to 6 months 1) Prevention of invasive diseases caused by pneumococcus (serotype 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) 2) Prevention of acute otitis media caused by pneumococcus (serotype 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) However, efficacy data for acute otitis media due to serotype 1, 3, 5, 6A, 7F, and 19A is not available. 3) Prevention of pneumonia caused by pneumococcus (serotype 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) 2. Prevention of invasive diseases caused by pneumococcus (serotype 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) in adults 50 years of age or older	For export
16	Manufactured	JETEMA THE TOXIN Inj. 100U (Clostridium Botulinum toxin type A) (for export)	Clostridium Botulinum Toxin Type A	JETEMA Co., Ltd.	2020-06-04	Temporary improvement of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activities in adults aged	For export

No.	Manufactured / Imported	Product	Ingredient	Company	Date of Approval	Efficacy/Effectiveness (Partially summarized)	Remarks
						between 19 and 65	
17	Manufactured	BTSA9(Clostrium botulinum toxin type A) (for export)	Clostridium Botulinum Toxin Type A	Protox Inc.	2020-08-13	porary improve-ment of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activities in adults aged between 19 and 65	For export
18	Manufactured	INIBO Inj. 100 Units (Clostridium Botulinum Toxin Type A) (for export)	Clostridium Botulinum Toxin Type A	Inibio Co., Ltd.	2020-09-21	porary improve-ment of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activities in adults aged between 19 and 65	For export
19	Manufactured	Toxnine Inj. 100 Unit (Clostridium Botulinum Toxin Type A) (for export)	Clostridium Botulinum Toxin Type A	MEDICA KOREA Co., Ltd.	2020-11-10	porary improve-ment of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activities in adults aged between 19 and 65	For export
20	Manufactured	ReNTox Inj. 200 Units (Clostridium Botulinum Toxin Type A) (for export)	Clostridium Botulinum Toxin Type A	Pharma Research BIO Co., Ltd.	2020-11-24	porary improve-ment of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activities in adults aged between 19 and 65	For export

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

3.2. Approval Status of Recombinant Protein Products

33 recombinant protein products were approved in 2020 (6 manufactured items and 27 imported items) including 5 new drugs (including new orphan drugs), 10 orphan drugs (excluding 4 new orphan drugs) and 18 drugs requiring data submission (including 3 items for export and 1 item of active pharmaceutical ingredient) (Refer to Table 40).

In 2020, items designated as new drugs (including new orphan drugs) were 3 ingredients and 5 items in total. New drugs approved in 2019 were 6 ingredients and 7 items, which shows a decrease in the

number of new drug approval in 2020. 6 ingredients and 10 items were approved for orphan drugs (excluding new orphan drugs) in 2020, and the number sharply increased compared to one item approval in 2019.

“Beovu Solution for Injection (brolucizumab)” (Novartis Korea, 2020.06.15), a vascular endothelial growth factor A (VEGF-A) inhibitor, was approved as a new drug that binds to the receptor binding area of the VEFG-A molecule to prevent interaction with VEGFR1 and VEGFR2 on the surface of epithelial cells and is used for the treatment of neovascular age-related macular degeneration.

“Ultomiris Inj. (ravulizumab)” (Handok Inc., 2020.05.21) is a monoclonal antibody with mechanisms where the drug specifically binds to complement component 5 (C5) to reduce the frequency of administration compared to Soliris Inj. (eculizumab), a previously approved drug with similar mechanisms of action, thereby improving treatment compliance. It is approved as a new orphan drug used in the treatment of paroxysmal nocturnal hemoglobinuria (PNH) in adults.

“CRYSVITA Solution for Injection 10 mg (burosumab, genetical recombination),” “CRYSVITA Solution for Injection 20 mg (burosumab, genetical recombination),” and **“CRYSVITA Solution for Injection 30 mg (burosumab, genetical recombination)”** (Kyowa Kirin Korea Co., Ltd., 2020.09.17) is a monoclonal antibody that restores phosphorus uptake in proximal tubules by binding to fibroblast growth factor 23 (FGF23) and neutralizing the action and increases serum phosphorus concentration by increasing 1,25(OH)2D production. These drugs were approved as new orphan drugs used for FGF23-related hypophosphatemia

rickets and osteomalacia.

“Emgality 100 mg/ml Pre-filled Syringe Injection (galcanezumab, recombinant)” (Lilly Korea, 2020.05.18) has the same active ingredient as 2 items including “Emgality 120 mg/ml Pre-filled Syringe Injection (galcanezumab, recombinant)” (efficacy/effectiveness: prevention of migraine in adults) which was previously approved in 2019, and it was approved as an orphan drug used for the reduction of cluster headache seizure during the cluster period in adult patients with intermittent cluster headache.

“Darzalex S.C Inj. (daratumumab)” (Janssen Korea Ltd., 2020.06.29) is an orphan drug developed in the form of subcutaneous injection with the same active ingredient and the same efficacy/effectiveness (treatment of multiple myeloma) as “Darzalex Inj. (daratumumab),” an intravenous infusion drug previously approved in 2017.

“Brineura Injection 150 mg (cerliponase alfa)” (MEDITIP, 2020.09.08) is an orphan drug used in treatment of type 2 neuronal ceroid lipofuscinosis (CLN2), also known as tripeptidyl peptidase 1 (TPP1) deficiency.

“SOMAVERT® Injection 10 mg (pegvisomant),” “SOMAVERT® Injection 15 mg (pegvisomant),” “SOMAVERT® Injection 20 mg (pegvisomant),” “SOMAVERT® Injection 25 mg (pegvisomant),” and **“SOMAVERT® Injection 30 mg (pegvisomant)”** (Pfizer Korea, 2020.09.16) are orphan drugs that reduce blood insulin-like growth factor-I (IGF-I) concentrations by reducing IGF-I secretion in hepatocytes and are used for the treatment of adult acromegaly in which an adequate response to

surgery and/or radiation therapy is not demonstrated and IGF-I levels are not normalized with somatostatin analogue treatment, or that does not have tolerance.

“Polivy Injection (polatuzumab vedotin)” (Roche Korea, 2020.10.27) is an antibody-drug conjugate and an anti-malignancy agent that preferentially delivers the potent antimitotic agent (MMAE) to B cells, and it was approved as an orphan drug used for combination therapy with bendamustine and rituximab in adult patients who are not suitable for stem cell transplants and have relapsed or refractory diffuse large B-cell lymphoma after one or more systemic treatments.

“Sarclisa Inj. (isatuximab)” (Sanofi-aventis Korea Co., Ltd., 2020.12.01) kills tumor cells by binding to CD38 receptors, and it was approved as an orphan drug used in combination therapy with pomalidomide and dexamethasone in patients with multiple myeloma who previously received more than two treatments, including lenalidomide and proteasome inhibitors.

For biosimilars, 3 ingredients and 4 items were approved. Since the approval of a monoclonal antibody biosimilar drug in 2012 for the first time in the world, a total of 17 types and 29 items were approved by 2019. Among them, there are a total of 11 types and 21 items of biosimilar products developed in Korea (Refer to Table 41).

“Adalloce 40 mg solution for injection in pre-filled pen” (Samsung Bioepis, 2020.07.03) is a biosimilar developed in Korea as a comparator for Humira Inj. 40 mg (adalimumab, recombinant protein) of AbbVie

Korea Ltd. in addition to **“Adalloce 40 mg solution for injection in pre-filled syringe”** which was approved on 2017.09.20.

“Ogivri Injection 150 mg” (Alvogen Korea Co. Ltd, 2020.08.26) is a biosimilar developed as a comparator for Herceptin Inj. 150 mg (trastuzumab) (monoclonal antibody, recombinant protein) of Roche Korea.

“Samfenet 440 mg powder for concentrate for solutionfor infusion” (Samsung Bioepis, 2020.10.14) is a biosimilar developed as a comparator for Herceptin Inj. 150 mg (trastuzumab) (monoclonal antibody, recombinant protein) of Roche Korea in addition to **“Samfenet 150 mg powder for concentrate for solution or infusion”** which was approved on 2017.11.08.

“Bemfola Prefilled Pen (Follitropin alfa)” (Yooyoung Pharm. Co., Ltd., 2020.10.29) is a biosimilar developed as a comparator for Gonal-F Pen Inj. (Follitropin alfa, recombinant protein) of Merck.

In 2020, the number of new drug approvals decreased slightly compared to 2019, but the number of orphan drug approvals increased significantly, and the overall number of recombinant proteins increased.

Table 40. List of Approved Recombinant Protein Products in 2020

No.	Manufactured /Imported	Product	Ingredient	Company	Date of Approval	Efficacy/Effectiveness (partially summarized)	Remarks
1	Imported	Beovu solution for injection	Brolucizumab	Novartis Korea	2020-06-15	Treatment of neovascular (wet) age-related macular degeneration	New drugs
2	Imported	Ultomiris Inj.	Ravulizumab	Handok Inc.	2020-05-21	Treatment of paroxysmal nocturnal hemoglobinuria (PNH) in adults	New orphan drugs
3	Imported	Crysvita solution for injection 10 mg (burosumab, genetical recombination)	Burosumab	Kyowa Kirin Korea Co., Ltd.	2020-09-17	FGF23-related hypophosphatemia rickets and osteomalacia	New orphan drugs
4	Imported	Crysvita solution for injection 20 mg (burosumab, genetical recombination)					New orphan drugs
5	Imported	Crysvita solution for injection 30 mg (burosumab, genetical recombination)					New orphan drugs
6	Imported	Emgality100mg/mL Prefilled Syringe Injection(Galcanezumab, Recombinant)	Galcanezumab	Lilly Korea	2020-05-18	Reduction of cluster headache seizure during the cluster period in adult patients with intermittent cluster headache	Orphan drugs
7	Imported	Darzalex S.C Inj.	Daratumumab	Janssen Korea Ltd.	2020-06-29	Combination therapy in patients with multiple myeloma	Orphan drugs
8	Imported	Brineura injection 150 mg (Cerliponase Alfa)	Cerliponase Alfa	MediTip Co., Ltd.	2020-09-08	Treatment of neuronal ceroid lipofuscinosis type 2 (CLN2)	Orphan drugs
9	Imported	SOMAVERT® Injection 10 mg	Pegvisomant	Pfizer Korea	2020-09-16	Treatment of adult acromegaly in which adequate response is not demonstrated to surgery and/or radiation therapy and IGF-I levels are not normalized with somatostatin analogue treatment, or which does not have tolerance	Orphan drugs
10	Imported	SOMAVERT® Injection 15 mg					Orphan drugs
11	Imported	SOMAVERT® Injection 20 mg					Orphan drugs
12	Imported	SOMAVERT® Injection 25 mg					Orphan drugs
13	Imported	SOMAVERT® Injection 30 mg					Orphan drugs
14	Imported	Polivy Injection (Polatuzumab vedotin)	Polatuzumab vedotin	Roche Korea Co., Ltd.	2020-10-27	Combination therapy of bendamustine and rituximab in adult patients with relapsed or refractory diffuse large B-cell lymphoma	Orphan drugs

No.	Manufactured /Imported	Product	Ingredient	Company	Date of Approval	Efficacy/Effectiveness (partially summarized)	Remarks
15	Imported	SARCLISA inj.	Isatuximab	Sanofi-aventis Korea Co., Ltd.	2020-12-01	Combination therapy with pomalidomide and dexa-methasone in patients with multiple myeloma who received more than two treatments	Orphan drugs
16	Imported	Adalloce 40 mg solution for injection in pre-filled pen	Adalimumab	Samsung Bioepis	2020-07-03	Rheumatoid arthritis, psoriatic arthritis etc.	Biosimilar
17	Imported	Ogivri Injection 150 mg	Trastuzumab	Alvogen Korea Co., Ltd.	2020-08-26	Breast cancer, metastatic gastric cancer	Biosimilar
18	Imported	Samfenet 440 mg powder for concentrate for solution for infusion	Trastuzumab	Samsung Bioepis	2020-10-14	Breast cancer, metastatic gastric cancer	Biosimilar
19	Imported	Bemfola prefilled pen.(follitropin alfa)	Follitropin-alfa	YooYoung Pharmaceutical Co., Ltd.	2020-10-29	Ovarian hyperstimulation during the adjuvant reproductive program and women's anovulation that is not treated with clomiphene citrate	Biosimilar
20	Imported	AFSTYLA injection	Lonoctocog Alfa (Blood coagulation factor VIII)	CSL Behring Korea Ltd.	2020-01-20	Prevention of bleeding in patients with type A hemophilia	Drugs requiring data submission
21	Manufactured	Epotin Plus Pre-filled Injection 10000IU/mL	Recombinant Human Erythropoietin	Alvogen Korea Co., Ltd.	2020-01-20	Anemia in patients with chronic renal failure	Drugs requiring data submission
22	Manufactured	Epotin Plus Pre-filled Injection 2000IU/0.5mL					Drugs requiring data submission
23	Imported	Remsima Pre-filled Syringe 120mg(Infliximab)(monoclonal antibody, recombinant DNA)	Infliximab	Celltrion, Inc.	2020-02-25	Crohn's disease, ankylsoing spondylitis, etc.	Drugs requiring data submission
24	Imported	Remsima Pre-filled Pen 120mg(Infliximab)(monoclonal antibody, recombinant DNA)	Infliximab	Celltrion, Inc.	2020-10-12	Crohn's disease, ankylsoing spondylitis, etc.	Drugs requiring data submission
25	Imported	IDELVION injection[Albutrepenonacog alfa (Fusion	Albutrepenonacog alfa (blood coagulation factor IX-albumin	CSL Behring Korea Ltd.	2020-03-05	Prevention of bleeding in patients with type B hemophilia	Drugs requiring data

No.	Manufactured /Imported	Product	Ingredient	Company	Date of Approval	Efficacy/Effectiveness (partially summarized)	Remarks
		protein linking blood coagulation factor IX with albumin (rIX-FP), recombinant)	recombination protein (rIX-FP))				submission
26	Imported	DUPIXENT 200mg solution for injection in pre-filled syringe	Dupilumab	Sanofi-aventis Korea Co., Ltd.	2020-05-06	Atopic dermatitis, asthma	Drugs requiring data submission
27	Imported	Beovu solution for injection in prefilled syringe (Brolucizumab)	Brolucizumab	Novartis Korea	2020-07-28	Treatment of neovascular (wet) age-related macular degeneration	Drugs requiring data submission
28	Imported	Lyumjev Injection 100unit/mL(Insullin lispro, Recombinant)	Insulin Lispro	Lilly Korea	2020-12-28	Adult diabetes	Drugs requiring data submission
29	Imported	Lyumjev Kwikpen Injection 100unit/mL(Insullin lispro, Recombinant)					Drugs requiring data submission
30	Manufactured	Remsima Subcutaneous Inj. (Drug Substance)	Infliximab	Celltrion, Inc.	2020-02-25	For drug preparation or manufacturing	Drug substance
31	Manufactured	Growtropin-II Injection (for export)	Recombinant human growth hormone	DONG-A ST	2020-07-24	Poor growth of children	For export
32	Manufactured	Growtropin-II Injection (Solution) (for export)					For export
33	Manufactured	Recombimax Inj. (for export)	Filgrastim	BORAN PHARMA	2020-10-30	Neutropenia, etc.	For export

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

Table 41. List of Approved Biopharmaceuticals (Biosimilars) (2012-2020)

No.	Product	Company	Comparator (ingredient)	Efficacy/ Effectiveness (partially summarized)	Date of Approval	Manufactured / Imported
1	Remsima Inj. 100mg(Infliximab)(monoclonal antibody,recombinant DNA)	Celltrion, Inc.	Remicade (Infliximap)	Rheumatoid arthritis, ulcerative colitis, etc.	2012-07-20	Manufactured
2	Herzuma Inj. 150mg(Trastuzumab)(monoclonal antibody,recombinant DNA)	Celltrion, Inc.	Herceptin Inj. (Trastuzumab)	Breast cancer, gastric cancer	2014-01-15	Manufactured
3	Herzuma Inj. 440mg(Trastuzumab)(monoclonal antibody,recombinant DNA)					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 change) 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 100unit/mL(Insulin Glargine, Recombinant)	Lilly Korea	Lantus (Insulin glargine)	Diabetes	2015.-11-25 (Withdrawn on 2019-09-26)	Imported
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. (Rituximab)(monoclonal antibody, recombinant DNA)	Celltrion, 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 change) Adalloce 40 mg solution for njection in pre-filled syring	Samsung Bioepis	Humira Inj. 40 mg (Adalimumab)	Rheumatoid arthritis, psoriatic arthritis, etc.	2017-09-20	Imported (developed in Korea)

No.	Product	Company	Comparator (ingredient)	Efficacy/ Effectiveness (partially summarized)	Date of Approval	Manufactured / Imported
	e					
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	Eucept Prefilled Syringe Inj.	LG Chem Ltd.	Enbrel (Etanercept)	Rheumatoid arthritis, psoriasis, etc.	2018-03-16	Manufactured
16	Eucept Autoinjector Inj.					Manufactured
17	NESBELL 20μg	Chong Kun Dang Pharm.	Nesp (Darbepoetin alpha)	Anemia in patients with chronic renal failure, etc.	2018-11-29	Manufactured
18	NESBELL 30μg					Manufactured
19	NESBELL 40μg					Manufactured
20	NESBELL 60μg					Manufactured
21	NESBELL 120μg					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 njection 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)
29	Bemfola prefilled pen.(follitropin alfa)	YooYoung Pharmaceutical Co., Ltd.	Gonal-F Pen Inj. (Follitropin-alfa)	Ovarian hyperstimulation, anovulation	2020-10-29	Imported

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

3.3. Approval Status of Cell Therapy Products

Since the domestically developed “Chondron” was approved as the first cell therapy product in Korea in 2001, a total of 16 products have been approved to date (Refer to Table 42). While “Cartilife” was approved in 2019, no cell therapy product was approved in 2020.

Since the Act on Safety and Support for Advanced Regenerative Medical and Advanced Biopharmaceuticals took effect on 2020.08.28, previously approved cell therapy products must obtain re-approval as advanced biopharmaceuticals by 2021.08.27.

As the enforcement of the Act established a periodic safety management system according to the characteristics of advanced biopharmaceuticals, customized safety management is expected and prompt treatment opportunities will be provided to patients with rare and incurable diseases.

Table 42. List of Approved Cell Therapy Products (2001-2020)

No.	Manufactured / Imported	Product	Ingredient	Company	Date of Approval	Efficacy/Effectiveness (partially summarized)	Remarks
1	Manufactured	Chondron	Autologous chondrocyte	Cellontech Co., Ltd	2001-01-30	Treatment of focal cartilage defect in knee joint (defect size: not more than 15 cm^2 in single lesion, not more than 20 cm^2 in multiple lesion)	
2	Manufactured	Holoderm	Autologous keratinocyte	Tego Science, Inc	2002-12-10	Creation of functional skin layer 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	

No.	Manufactured / Imported	Product	Ingredient	Company	Date of Approval	Efficacy/Effectiveness (partially summarized)	Remarks
3	Manufactured	Kaloderm	Allogeneic keratinocyte	Tego Science, Inc	2005-03-21	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	Manufactured	Keraheal	Basol autologous keratinocyte	Biosolution Co., Ltd.	2006-05-03	Creation of functional skin layer 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	Manufactured	CreaVax-RCC Inj.	Autologous dendritic cell	JW CreaGene	2007-05-15	Metastatic renal cell carcinoma capable of nephrectomy	For export
6	Manufactured	Immuncell-LC	LC autologous blood origin T lymphocyte	GC Cell	2007-08-06	Adjuvant therapy for patients whose tumor has been removed after curative resection for hepatocellular carcinoma (operation, radio frequency ablation, percutaneous ethanol injection therapy)	
7	Manufactured	RMS Ossron	Autologous osteoblast	Cellontech Co., Ltd	2009-08-26	Promoting local bone formation	
8	Manufactured	Queencell	Minimally manipulated autologous adipose tissue-derived fat cell	Anterogen. Co., Ltd	2010-03-26	Improvement of subcutaneous fat defect	
9	Manufactured	CureSkin Inj.	Autologous dermal fibroblast	S.Biomedics Co., Ltd.	2010-05-11	Improvement of dented scar area came from the acne treatment process	
10	Manufactured	Hearticellgram - AMI	Autologous bone marrow-derived mesenchymal stem cell	Pharmicell Co., Ltd.	2011-07-01	Improvement of left ventricular ejection fraction in patients who had reperfused acute myocardial infarction by coronary angioplasty within 72 hours after chest pain	
11	Manufactured	CARTISTEM	Allogenic umbilical cord blood-derived mesenchymal stem cell	MEDIPOST Co., Ltd.	2012-01-18	Treatment of knee cartilage defects in patients with degenerative or repetitive traumatic osteoarthritis (ICRS grade IV)	

No.	Manufactured / Imported	Product	Ingredient	Company	Date of Approval	Efficacy/Effectiveness (partially summarized)	Remarks
12	Manufactured	Cupistem	Autologous adipose-derived mesenchymal stem cell	Anterogen. Co., Ltd	2012-01-18	Treatment of fistula due to Crohn's disease	Orphan drugs
13	Manufactured	Neuronata-R ® inj. (Autologous bone marrow-derived mesenchymal stem cells)	Autologous bone marrow-derived mesenchymal stem cell	Corestem Inc.	2014-07-30	Alleviate the disease progre-ssion rate of amyotrophic lateral sclerosis in combination with riluzole	Orphan drugs
14	Manufactured	Keraheal-Allo	Bosol allogeneic keratinocyte	Biosolution Co., Ltd.	2015-10-16	Promoting re-epithelization of deep second degree burn	
15	Manufactured	Rosmir	Tego autologous fibroblast	Tego Science, Inc	2017-12-27	Improvement of moderate-to-severe nasojugal groove	
16	Manufactured	Cartilife	Basol autologous cartilage-derive d chondrocyte	Biosolution Co., Ltd.	2019-04-24	Treatment of knee cartilage defect (ICRS grade III or IV, defect area 2 to 10 cm^2)	

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

4

Approval Status of Herbal Medicinal Preparations

4. Approval Status of Herbal Medicinal Preparations

In 2020, a total of 64 herbal medicinal preparation items were approved. As compared with 31 items in 2016, 44 items in 2017, 42 items in 2018 and 56 items in 2019, the number was increased by 106.5%, 45.5%, 52.4% and 14.3%, respectively (Refer to Table 43).

The approval by review type is analyzed as follows: 5 drugs requiring data submission, including 3 drugs with new composition and 2 drugs with a change in strength. In addition, the highest number was drugs approved based on equivalence data from bioequivalence tests, etc. (47 items), followed by drugs approved for herbal health insurance medicine based on prescriptions in Korean traditional medicine books (2 items), new dosage forms (6 items including extract concentrate, tablet, and liquid), and herbal substances (4 items).

Table 43. Approval of Herbal Medicinal Preparations by Review Type in 2020

(Unit: number of items)

<table>
<tr><th>Type</th><th colspan="3">Review Type</th><th colspan="2">No. of Approved Items</th></tr>
<tr><td>1</td><td rowspan="2">New drugs (0)</td><td colspan="2">New drugs</td><td colspan="2">0</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 requiring data submission</td><td colspan="2">5</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="8">Drugs requiring data submission</td><td colspan="2">New composition and specification</td><td rowspan="8">5</td><td>3</td></tr>
<tr><td>4-3</td><td colspan="2">Change in strength</td><td>2</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>0</td></tr>
<tr><td>4-7</td><td colspan="2">Literature evidence other than Korean traditional medicine books</td><td rowspan="2">0</td></tr>
<tr><td>4-8</td></tr>
<tr><td>5</td><td colspan="4">Proof of equivalence</td><td colspan="2">47</td></tr>
<tr><td rowspan="3">6</td><td rowspan="3">Others</td><td colspan="2">Prescriptions in Korean traditional medicine books</td><td rowspan="3">12</td><td>8</td></tr>
<tr><td colspan="2">Active pharmaceutical ingredients</td><td>0</td></tr>
<tr><td colspan="2">Herbal substances</td><td>4</td></tr>
</table>

* Excluding drugs for export only (1 item)

Moreover, the approvals by drug classification were analyzed as follows: ETC drugs (50 items), OTC drugs (10 items), and herbal substances (4 items) (Refer to Table 44).

Table 44. Approval Status of Herbal Medicinal Preparations in 2020

(Unit: number of items)

Type	Category	Total	Item Approval			
			ETC	OTC	API	Herbal substance
Total		64	50	10	0	4
Herbal medicinal preparations	Manufactured	64	50	10	0	4
	Imported	0	0	0	0	0

* Excluding drugs for export only (1 item)

4.1 Approval Status of Herbal Medicinal Preparations as ETC Drugs

Among the herbal medicinal preparations approved in 2020, ETC drugs comprised 50 domestically manufactured items with 3 ingredients.

15 items including **"Stoem 2X Tab. (Artemisia Herb 95% Ethanol Soft Ext. (20→1))"** (Mother's Pharmaceutical Co. LTD, 2020.04.24) are generic drugs of "Stillen 2X Tab. (Artemisia Herb 95% Ethanol Soft Ext. (20→1)" which was approved in 2015. This product was approved for the purpose of improving gastric mucosal lesions (maceration, bleeding, redness and edema) due to acute gastritis and chronic gastritis.

3 items including **"LOMINCOMP Syrup"** (Korea United Pharm. Inc., 2020.03.13) are combination drugs containing pelargonium sidoides 11% ethanol extract (1→ 8-10) and coptidis rhizoma dried extract

(8.93→1), and they were approved for the purpose of treatment of acute bronchitis.

19 items including **“S To-3 Soft Cap. (Omega-3-Acid Ethyl Esters90)”** (Korea Syntex, 2020.01.06) are generic drugs of “Omacor Soft Cap. (Omega-3-Acid Ethyl Esters90)” which was approved in 2005. This product was approved as a dietary supplement to prevent recurrent development after myocardial infarction and to reduce elevated triglyceride levels in patients with endogenous hypertriglyceridemia. And 13 other items such as **“Newmetin Mini Soft Cap. (Omega-3-Acid Ethyl Esters90)”** (Reyon Pharmaceutical Co. LTD, 2020.01.31) were approved as generic drugs of “Omacormini Soft Cap. 2 g (Omega-3-Acid Ethyl Esters90).”

4.2 Approval Status of Herbal Medicinal Preparations as OTC Drugs

Among 10 herbal medicinal preparations approved as OTC drugs in 2020, 2 items were manufactured as “solitary extract mixture” preparations based on prescriptions in Korean traditional medicine books, 2 items were prepared into tablets, 4 items were prepared into soft extracts, and 2 items were drugs with change in strength.

4.3 Approval Status of Herbal Medicinal Preparations Requiring Data Submission

Drugs requiring data submission are those that are not new drugs, but need to be reviewed for safety and efficacy, and include

▲injectables/transdermal drugs belonging to ETC drugs with no prescription evidence, ▲herbal medicinal preparations with new compositions and specifications, ▲changed in strength single drugs/ combination drugs, ▲drugs belonging to new therapeutic classes, ▲active substances with new compositions or changes in strength, ▲ drugs with new administration routes, ▲drugs with new modes of administration/ dosage, ▲drugs with new administration routes, ▲new dosage forms (same administration route).

Among the drugs requiring data submission approved in 2020, the development of drugs with new compositions made up the largest proportion (60.0%, 3 items), followed by drugs with a change in strength (40.0%, 2 items) (Refer to Table 45).

Table 45. Approval Status of Drugs Requiring Data Submission in 2020

Review Type of Drugs Requiring Data Submission	No. of Approved Items
New composition of active substances	3
Changes in strength of active substances	2
Total	5

1) Drugs with new compositions of active substances (3 items)

3 respiratory system drugs (3 manufactured items) were approved as drugs with new compositions. These were developed as combinations of pelargonium sidoides and coptidis rhizoma to increase compliance with medication by allowing patients to take two substances at once and to simultaneously conduct causal treatment and symptomatic treatment of acute bronchitis (Refer to Table 46).

Table 46. Approval Status of Drugs with New Composition that Require Data Submission in 2020

No.	Manufactured / Imported	Product	Company	Date of Approval	Classification Code	Active Ingredient
1	Manufactured	LOMINCOMP Syrup	Korea United Pharm. Inc.	2020-03-13	[229] Miscellaneous respiratory organ drugs	Pelargonium sidoides 11% ethanol extract (1→8-10) Coptidis Rhizoma Dried Extract (8.93→1)
2	Manufactured	Pelaum S Syrup	Hanmi Pharm. Co., Ltd.	2020-06-30		
3	Manufactured	PELANIN COMP Syrup.	KOREA BIOCHEM PHARM. INC.	2020-06-30		

2) Drugs with change in strength only (2 items)

2 items (2 manufactured items) were approved as new drugs with a change in strength, where the mode of administration/dosage of Ginkgo Leaf Dried Ext. Tab. was changed from twice a day to once a day by increasing the strength from the previously approved 120 mg to 240 mg (Refer to Table 47).

Table 47. Approval Status of Drugs with Changes in Strength of Active Substances that Require Data Submission in 2020

No.	Manufactured/ Imported	Product	Company	Date of Approval	Classification Code	Active Ingredient
1	Manufactured	Ginkgopil Tab. 240mg (Ginkgo Leaf Dry Extract)	RICHWOOD TRADING COMPANY, LTD.	2020-11-13	[219] Miscellaneous cardiovascular drugs	Ginkgo Leaf Dry Extract
2	Manufactured	Ginexin F tab 240 mg (Ginkgo Leaf Dry Extract)	SK Chemicals	2020-12-24		

4.4 Approval Status of Active Pharmaceutical Ingredients and Herbal Substances

No item was approved as an active pharmaceutical ingredient, and 4 items including “Pelodiscis Carapax Preparata cum Acetum” were approved (Refer to Table 48).

Table 48. Approval Status of Herbal Medicinal Preparations in 2020 (Active Pharmaceutical Ingredients and Herbal Substances)

No.	Manufactured/ Imported	Product	Company	Date of Approval	Efficacy/ Effectiveness	Remarks
1	Manufactured	Pelodiscis Carapax Preparata cum Acetum	HUMAN HERB CO., LTD	2020.02.06	Miscellaneous drugs for compounding	Herbal substances
2	Manufactured	Corydalis Tuber Preparata cum Acetum	HUMAN HERB CO., LTD	2020.02.06	Miscellaneous drugs for compounding	Herbal substances
3	Manufactured	Plantaginis Semen Preparata	HUMAN HERB CO., LTD	2020.02.06	Miscellaneous drugs for compounding	Herbal substances
4	Manufactured	Testudinis Chinemis Plastrum et Carapax Preparata cum Acetum	HUMAN HERB CO., LTD	2020.02.06	Miscellaneous drugs for compounding	Herbal substances

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

Appendix Information on Departments Responsible for Pharmaceutical Petitions, Etc.

Table 49. Information on Departments Responsible for Pharmaceutical Petitions, Etc. (As of April 2021)

Category	Department	Detailed Petition Service
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 Novel Products Approval		·Approval of biologics, recombinant protein products, gene therapy products, cell therapy products, tissue engineering drugs and quasi-drugs for manufacturing/marketing and import ·Approval of manufacturing and import according to types and items 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 (medical products of convergence) ·Operation of bio-drugs, quasi-drugs, medical devices, and medical products of convergence, and approval system ·Orders of re-review on medical devices
Pharma-ceutical Safety Bureau	Pharmaceutical Policy Division	·Designation of orphan drugs
	Pharmaceutical Management Division	·Drug marking and 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 active pharmaceutical ingredient (DMF)
	Clinical Trials Policy Division	·Approval of clinical trial protocols ·Inspection of clinical trials

Category	Department	Detailed Petition Service
		·Control of clinical trial sites and non-clinical (GLP) institutions
	Narcotics Policy Division	·Approval of manufacturing and import/export of narcotic drugs and items ·Quality control of narcotic drugs ·Designation of temporary narcotics
	Narcotics Management Division	·Follow-up management of narcotics
NIFDS	Pre-Submission Consultation Division	·Pre-submission consultation on the application for protocol approval of drugs subject to expedited review and INDs (including biologics, recombinant proteins, herbal medicinal preparations) ·Pre-submission consultation on the application for item approval of drugs subject to expedited review and INDs ·Pre-submission consultation on the application for protocol approval of medical devices (excluding software-based medical devices and in vitro diagnostic devices) subject to expedited review ·Pre-submission consultation on the application for item approval of medical devices subject to 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 Devices	·Review of application for designation of drugs (including biologics, recombinant proteins, herbal medicinal preparations) subject to expedited review ·Review of application for designation of medical devices (excluding software-based medical devices and in vitro diagnostic devices) subject to expedited review ·Expedited review of quality and safety/efficacy of drugs designated for expedited review ·Expedited review of technical documents and clinical study data of medical devices designated for expedited review

Category	Department		Detailed Petition Service
			·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 for active pharmaceutical ingredients (excluding ingredients of new drugs) ·Quality review of generic drugs ·Review of specifications and test methods of the following drug products 710 Drugs for prescription 731 Preservatives 741 Capsules 799 Drugs not classified separately and not primarily used for treatment (those not containing safety and efficacy review) ·Review of equivalence study data for active ingredient manufacturer change (addition) with no change in manufacturing processes
		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 Cardiovascular 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 protocols ·Preliminary review ·Re-evaluation, re-review, and review of RMP periodic report and PSUR
		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

Category	Department		Detailed Petition Service
			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 protocols ·Preliminary review ·Review of re-evaluation of re-review data
		Advanced Drug Quality Division	·Review of quality of new drugs, orphan drugs, drugs requiring data submission, etc. ·Review of registration data of active pharmaceutical ingredients (new substances and its salts) ·Quality review of clinical trial protocols ·Quality review of drugs included in medical products of convergence ·Quality review of radiopharmaceuticals ·Preliminary review on quality of drugs under the jurisdiction ·Review of equivalence study data for active ingredient manufacturer change (addition) with no change in manufacturing processes for the drugs under the jurisdiction
		Bioequivalence Evaluation Division	·Review of biological equivalence test plan ·Review of biological equivalence test result report ·Reliability Review of biological equivalence test ·Review of biological equivalence test for re-evaluation ·Review of drug equivalency test result report (including manufactured (imported) item approvals (notifications)/changes) ·Review of drug equivalence test result report (approval/notification) ·Safety/efficacy review and review of clinical trial protocols of digestive system drugs (230) Safety/efficacy review and review of clinical trial protocols of miscellaneous metabolic drugs (390) ·Preliminary review

Category	Department		Detailed Petition Service
			·Review of re-evaluation of re-review result report ·Review of periodic report and result of risk management plan and PSUR review
Biopharma-ceuticals and Herbal Medicine Bureau	Biopharmaceutical Quality Management Division		·GMP evaluation and guidance for manufacturers and manufactured/imported items of biologics, etc. ·Inspection of active pharmaceutical ingredients (DMF) subject to 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		·Quasi-drug GMP evaluation
NIFDS	Biopharm-ceuticals and Herbal Medicine Evaluation Department	Biologics Division	Biologics and human placenta-derived drugs ·Quality and safety/efficacy review ·Review of clinical trial protocols ·Preliminary review ·Review of re-evaluation of re-review result report
		Recombinant Protein Products Division	Recombinant Protein Products ·Quality and safety/efficacy review ·Review of clinical trial protocols ·Preliminary review ·Review of re-evaluation of re-review result report
		Cell and Gene Therapy Products Division	Cell therapy, gene therapy, etc. ·Quality and safety/efficacy review ·Review of clinical trial protocols ·Preliminary review ·Review of re-evaluation of re-review result report
		Herbal Medicinal Products Division	Herbal medicinal preparations, etc. ·Quality and safety/efficacy review ·Review of drug equivalence (including bioequivalence test) ·Review of clinical trial protocols ·Preliminary review ·Review of re-evaluation of re-review data
		Cosmetics Evaluation Division	Functional cosmetics ·Quality and safety/efficacy review ·Actual data review of cosmetics labelling/advertisement

Category	Department		Detailed Petition Service
			and quasi drugs ·Quality and safety/efficacy review ·Preliminary review ·Review of re-evaluation data

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Introduction of Public Interest Reporter Protection System

The Public Interest Reporter Protection Act always protects your conscience.
If a public official or representative of the Ministry of Food and Drug Safety has committed an irregularity or handled any issue unfairly, please report it as follows. We guarantee the identity of the reporter and promise to do our best to ensure that there is no inconvenience in handling civil complaints in the future.

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A system for protecting public interest reporters, etc. (including relatives or partner) through **confidentiality, disadvantage protection measures, personal protection measures,** etc. so that they are not harmed by public interest reports, etc.

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