2018

Drug Approval Report

May, 2019

Ministry of Food and Drug Safety

Innovative Convergence Products Support Department

Approval Management Team

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This 2018 Drug Approval Report is to support the systematization and efficiency of establishment/enforcement of related regulations and drug approval/notification; and product development by sharing the information on approval/notification of all drugs in line with the 2017 Drug Approval Report.

1.1. General Information

First, according to the approval/notification information on all drugs in 2018 including chemical drugs, biopharmaceuticals and herbal medicinal products, a total of 2,482 items were approved and notified as shown in Table 1. The total number of items decreased by 42 items (1.7%) YoY, but the overall status of drug approval/notification was similar to that of 2017.

Table 1. Outline of Drug Approval/ Notification Status (2017~2018)

(Unit: number of items)

Year	Total	Approval	Notification	Head quarters	Regional Office	Mfg.	Imported	Finished	Drug substances (excluding herbal substances)	Herbal substances	Finished drug product	
											Prescribed	OTC
'17	2,524	1,315 (52.1%)	1,209 (47.9%)	361 (14.3%)	2,163 (85.7%)	2,360 (93.5%)	164 (6.5%)	2,049 (81.2%)	55 (2.2%)	420 (16.6%)	1,573 (76.8%)	476 (23.2%)
		excluding herbal substances (420)		excluding herbal substances (420)		excluding herbal substances (420)		excluding herbal substances(%)				
		1,306 (62.1%)	798 (37.9%)	352 (16.7%)	1,752 (83.3%)	1,940 (92.2%)	164 (7.8%)	97.4%	2.6%			
'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* Excluding drugs for export (79 items), including revoked and withdrawn items and herbal substances

Of the total items, the approved items are 55.6% (1,379 items) and the notified items are 44.4% (1,103 items). According to analysis by agency, the items approved by the Headquarters were 16.0% (397 items)

while the items approved by and notified to the regional office were 84.0% (2,085 items), which show the approved and notified items of the regional offices were larger than those of the Headquarters.

It was found the manufactured and marketed drugs were 95.1% (2,360 items) and the imported drugs were 4.9% (122 items). Finished drug products were 82.4% (2,046 items), drug substances 3.0% (75 items), and herbal substances 14.6% (361 items). Finished drugs (96.5%) were significantly larger than drug substances (3.5%) when excluding herbal substances, and the prescription drugs amounted to 74.0% (1,514 items) and the over-the-counter (OTC) drugs to 26.0% (532 items) respectively.

It was also confirmed the ratio of approved and notified generic drugs still remain high in the total approved and notified items considering the drugs approved by/notified to regional offices recorded a higher rate of 84.0% to the total items. Like 2017, the approval/notification status in 2018 shows the domestically manufactured prescription drugs took the most. However, while the number of drugs approved by the Headquarters increased by 36 items (10%) year on year, those notified to regional offices decreased by 106 items (8.8%).

The annual status of drug approval/ notification since 2010 is as shown in Table 2 and Figure 1 below. In general, the number of approved items (excluding herbal substances) in 2018 was 1,378 items, which showed a slight increase from 1306 in 2017, but no significant change.

As for the notified items (excluding herbal substances), thanks to an introduction of preliminary GMP on OTC drugs since July 1, 2009, the number of items reported in 2011(753 items) significantly reduced to almost half of that in 2010(1,530 items), but since then there was no significant change. In 2018, 743 items were notified, decreased by 6.9% from 798 in the previous year.

In addition, in case of notification herbal substances, as the simple processing/ packing of herbal substances became subject to notification from October, 2011, the number of item notification in 2011 increased about twice more than that of 2010 but has been gradually decreased from 2012. The number of items increased since 2015, which seems to be an influence of the pilot introduction period (GMP evaluation only for new items, June, 2012 - December, 2014,) before the full-fledged GMP evaluation for herbal substances (January 1, 2015). In 2018, it was 1,103 items decreased by 8.8% (106 items) from 1,209 items in 2017.

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

(Unit: number of items)

Category	2010	2011	2012	2013	2014	2015	2016	2017	2018
Approval	614	853	831	1,423	1,811	2,110	2,030	1,306	1,378 (65.0%)
(increase % YoY)		38.9%	-2.5%	71.2%	27.3%	16.6%	-3.8%	-35.7%	5.5%

Notification	1,530	753	687	787	1,118	904	815	798	743 (35.0%)
(increase % YoY)	-50.7%	-8.7%	14.6%	42.1%	-19.1%	-9.8%	-2.1%	-6.9%	
Total	2,144	1,606	1,518	2,210	2,929	3,014	2,845	2,104	2,121
(increase % YoY)	-25.0%	-5.4 %	45.6%	32.5%	2.9%	-5.6%	-26.0%	8.1%	

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

Table 2-2 Number of drug approvals/ notifications by year (including Herbal Substance)

(Unit: number of items)

Category	2010	2011	2012	2013	2014	2015	2016	2017	2018
Approval	618	853	835	1,423	1,811	2,110	2,036	1,315	1,379 (55.6%)
(increase % YoY)	38.0%	-2.1%	70.4%	27.3%	16.6%	-3.5%	-35.4%	4.9%	
Notification	3,497	7,269	3,898	973	1,296	2,813	1,792	1,209	1,103 (44.4%)
(increase % YoY)	107.8%	-46.3%	-75.0%	33.2%	117.1%	-36.3%	-32.5%	-8.8%	
Total	4,115	8,122	4,733	2,396	3,107	4,923	3,828	2,524	2,482
(increase % YoY)	97.4%	-41.7%	-49.4%	29.7%	58.4%	-22.2%	-34.1%	-1.7%	

* Excluding drugs for export, including revoked/withdrawn items

Table 2-3. Notification status of in Herbal Substance by year

(Unit: number of items)

Category	2010	2011	2012	2013	2014	2015	2016	2017	2018
Herbal substances	1,967	6,516	3,211	186	178	1,909	983	420	361
(increase % YoY)	231.3%	-50.7%	-94.2%	-4.3%	972.5%	-48.5%	-57.3%	-14.0%	
All notified items herbal substances	3,497	7,269	3,898	973	1,296	2,813	1,792	1,209	1,103

* Excluding drugs for export, including revoked/withdrawn items

Figure 1-1. Number of Drug Approval and Notification (2010~2018) (Excluding Herbal Substances)

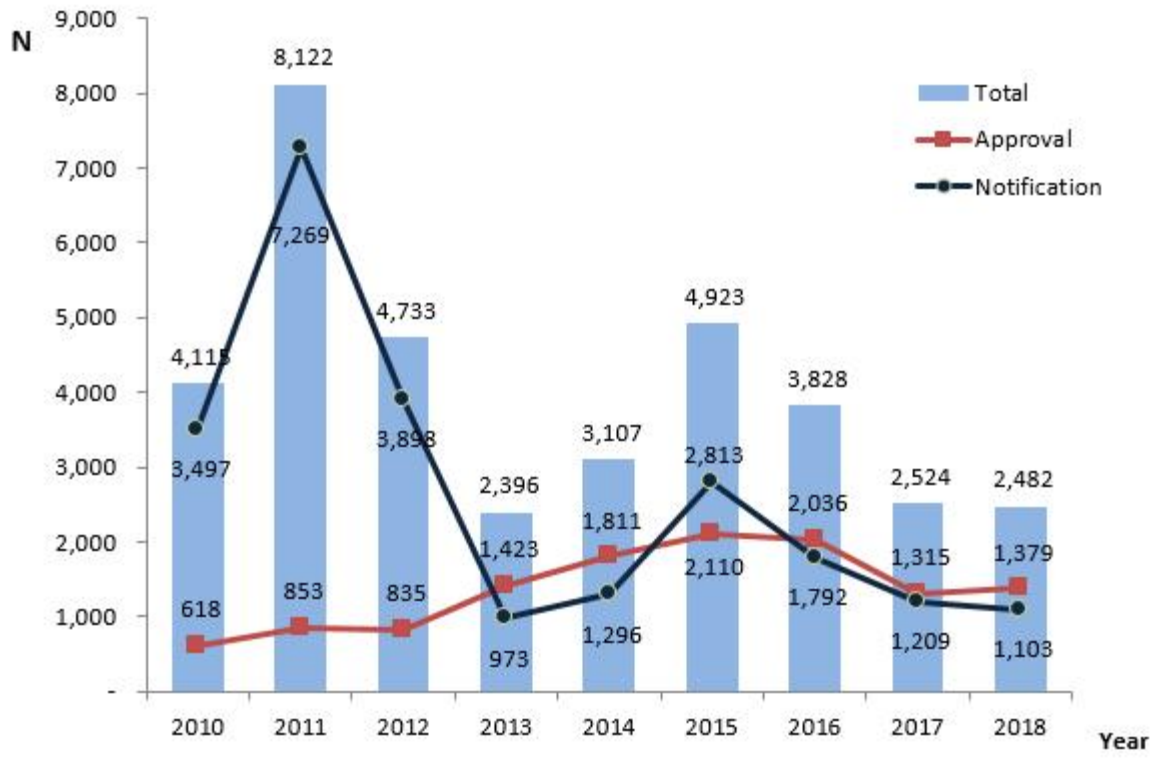


Figure 1-2. Number of Drug Approval and Notification (2010~2018) (Herbal Substances)

To analyze the approval and notification of medical products of 2018 in detail, it was found the items approved by regional offices was 982 items (71.3%) out of total 1,378 approved items, which is about 2.5 times more than the items approved by the Headquarters 396 items (28.7%) (Refer to Table 3-1).

This means that the number of approval cases of generic drugs, which is subject to the approval of regional offices, is relatively higher than that of drugs requiring for data submission. In addition, 99% of 982 drugs approved by regional offices were the manufactured items (974 items) (Refer to Table 3-2).

Table 3-1. Drug Approval/ Notification Status by Institution in 2018

(Unit: number of items)

Type	Total	Headquarters	Regional Office
Approval	1,378 (100%)	396 (29%)	982 (71%)
Notification	743	-	743
herbal substances	361	1	360
Total	2,482 (100%)	397 (16%)	2,085 (84%)

* Excluding drugs for export (79 items), including revoked/withdrawn items and herbal substances

Table 3-2. Outline of Drug Approval and Notification in 2018

(Unit: number of items)

<table>
<tr><th colspan="4">Domestically manufactured (1,999 items)</th><th colspan="4">Imported (122 items)</th></tr>
<tr><td rowspan="5">Finished (1,962)
98%</td><td rowspan="3">Prescribed (1,440)
72%</td><td rowspan="2">Approval (1,236)</td><td>Headquarters (263)</td><td rowspan="5">Finished (84)
69%</td><td rowspan="3">Prescribed (74)
61%</td><td rowspan="2">Approval (71)</td><td>Headquarters (63)</td></tr>
<tr><td>Regional Office (973)</td><td>Regional Office (8)</td></tr>
<tr><td>Notification (204)</td><td>Regional Office (204)</td><td>Notification (3)</td><td>Regional Office (3)</td></tr>
<tr><td rowspan="3">OTC (522)
26%</td><td rowspan="2">Approval (38)</td><td>Headquarters (37)</td><td rowspan="3">OTC (10)
8%</td><td rowspan="2">Approval (4)</td><td>Headquarters (4)</td></tr>
<tr><td>Regional Office (1)</td><td>Regional Office (0)</td></tr>
<tr><td>Notification (484)</td><td>Regional Office (484)</td><td>Notification (6)</td><td>Regional Office (6)</td></tr>
<tr><td rowspan="2">Raw materials (37)
2%</td><td>Approval (21)</td><td>Headquarters (21)</td><td rowspan="2">Raw materials (38)
31%</td><td>Approval (8)</td><td>Headquarters (8)</td></tr>
<tr><td>Notification (16)</td><td>Regional Office (16)</td><td>Notification (30)</td><td>Regional Office (30)</td></tr>
</table>

* Excluding drugs for export(79 items) and herbal substances(361 items), including revoked/withdrawn items

In terms of the approvals and notifications by regional office, Kyungin Office took 38.5% (802 items) the largest number of items processed, followed by Daejeon Office with 30.1% (629 items) respectively. Most of the total approvals and notifications (70%) were handled in Kyungin Office and Daejeon Office and in case of herbal substances, most of them (68.9%, 248 items) were handled by Seoul Office (Refer to Table 4).

Table 4. Details of Drug Approval and Notification in Regional Offices in 2018

(Unit: number of items)

Item		Approval	Notification	herbal substances	Total
Regional Office	Kyungin	482 (49.1%)	319 (42.9%)	1 (0.3%)	802 (38.5%)
	Daejeon	358 (36.5%)	270 (36.3%)	1 (0.3%)	629 (30.1%)
	Seoul	70 (7.1%)	48 (6.5%)	248 (68.9%)	366 (17.6%)
	Busan	40 (4.1%)	28 (3.8%)	28 (7.8%)	96 (4.6%)
	Daegu	16 (1.6%)	17 (2.3%)	25 (6.9%)	58 (2.8%)
	Gwangju	16 (1.6%)	61 (8.2%)	57 (15.8%)	134 (6.4%)
Total		982 (100%)	743 (100%)	360 (100%)	2,085 (100%)

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

The analysis of the manufacturing drugs and imported drugs shows that the manufacturing items was similar ratio of the approved items (55%) and notified items (45%) but, in case of imported items, the approval items (68%) was about two(2) times more than the notified item (32%) (Refer to Table 5).

Table 5. Information on Drug Manufacture and Import in 2018

(Unit: number of items)

Item	Total	Manufactured	Imported
Approved	1,379	1,296 (55%)	83 (68%)

Declared	1,103	1,064 (45%)	39 (32%)
Total	2,482	2,360 (100%)	122 (100%)

* Excluding drugs for export (79 items), including revoked/withdrawn items and herbal substances

According to the analysis of finished drugs and drug substances of approved/ notified items, in case of finished drugs, 66% (1,349 items) was approved items while, in case of the drug substances, (excluding herbal substance), only 39% (29 items) was approved items and the rest 61% is notification items (Refer to Table 6).

Table 6. Details of Finished Products and Drug Substances Approval/ Notification in 2018

(Unit: number of items)

Item	Total	Finished	Drug substances (including herbal substances)	Drug substances (excluding herbal substances)
Approval	1,379	1,349 (66%)	30 (7%)	29 (39%)
Notification	1,103	697 (34%)	406 (93%)	46 (61%)
Total	2,482	2,046 (100%)	436 (100%)	75 (100%)

* Excluding drugs for export (79 items), including revoked/withdrawn items

From the analysis of types of drugs in finished drugs (approved and notified), it was found chemical drugs took 92.2% (1,886 items) followed by biopharmaceuticals 1.4% (28 items) and herbal medicinal products 6.4% (132 items) (Refer to Table 7).

Table 7. Classification of Chemicals, Biopharmaceuticals and Herbal Substances from Finished Drugs in 2018

(Unit: number of items)

Item	Total [1)]	Chemical drugs[2)]	Biopharmaceuticals [3)]	Herbal medicinal products [4)]
Finished	**2,046**	**1,886 (92.2%)**	**28 (1.4%)**	**132 (6.4%)**

1) Excluding drugs for export only (79 items), including revoked/withdrawn items
2) Out of 1,886 items, 328 items were approved by the Headquarters
3) In Table 37 and Table 38, List of approved biopharmaceuticals, all 36 items (including 6 items for export only) were approved by the Headquarters
4) Out of 132 items, 11 items were approved by the Headquarters. Table 44 and Table 45, 2018 approval of herbal medicinal products and herbal substances approval information show 42 items (including 2 drug substance items and 1 herbal substance item)

Of the finished medical products, the number of new drugs (including orphan new drugs) was 15 items (0.7%), orphan drugs (excluding new drugs) was 13 items (0.6%), drugs requiring data submission was 264 items (12.9%), and generic drugs was 1,754 items (85.7%), which shows the ratio of generic drugs is relatively high as in 2017 (Table 8). However, drugs requiring data submission approved in 2018 (264 items) increased by 47 items (21.7%) from 2017 (217 items). In addition, 6 incrementally modified drugs from drugs requiring data submission and 8 listed items of herbal medicinal products were approved (Refer to Table 8).

Table 8. Classification of New Drugs, Drugs Requiring for Data Submission and Generic drugs in 2018

(Unit: number of items)

<table>
<tr><th rowspan="2">Item</th><th rowspan="2">Types</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</th><th>Orphan new drugs</th><th>Orphan drugs</th><th>incrementally modified drugs (IMD)</th><th>drugs requiring for data submission</th><th>Herbal medicinal products based on Herbal Medicine Book</th><th>(Head quarters)</th><th>(Regional Office)</th></tr>
<tr><td rowspan="3">Finished</td><td>Chemical
1,886</td><td>8</td><td>3</td><td>11</td><td>6</td><td>233</td><td></td><td>67 [4]</td><td>1,558 [5]</td></tr>
<tr><td>Biopharmaceuticals
28 [7]</td><td>3</td><td>1</td><td>1</td><td></td><td>23 [6]</td><td></td><td></td><td></td></tr>
<tr><td>herbal medicinal products
132 [8]</td><td></td><td></td><td>1</td><td></td><td>2</td><td>8</td><td></td><td>121</td></tr>
<tr><td rowspan="2">Total</td><td rowspan="2">2,046 [1]
(100%)</td><td>11</td><td>4 [3]</td><td rowspan="2">13
(0.6%)</td><td>6</td><td>258</td><td>8</td><td>67</td><td>1,681</td></tr>
<tr><td colspan="2">15 [2] (0.7%)</td><td colspan="2">264 (12.9%)</td><td colspan="3">1,754 (85.7%)</td></tr>
</table>

1) Excluding drugs for export (79 items), including revoked/withdrawn items

2) 15 items are new drugs approved in 2018 and there no approved change in new drugs (removed from orphan drug designation).
3) It is a new drug ingredients designated as both orphan drug and new drug.
4) Special formulations, generic drugs for narcotic drugs, and items that exempt safety and efficacy review, etc.
5) Standard manufacturing standard items, generic (excluding special formulations and drugs) drugs
6) Cell therapy products and human placenta-derived drugs
7) In Table 37 and Table 38, 2018 list of biopharmaceuticals approved includes 36 items (including 6 items for export only) approved by the Headquarters
8) Out of 132 items, 11 items were approved by the Headquarters. In table 44 and table 45 "Information on Approval of Herbal Medicinal Products 2018", there are 42 items (including drug substances, 1 herbal substance).

Table 9. Details of the Headquarters Approval Items in 2018 (Finished Drugs)

(Unit: number of items)

Types	Total	Manufactured	Imported
the Headquarters approval (Finished)	367	300	67
Chemical	328 (89.4%)	275	53
Biopharmaceuticals	28 (7.6%)	15	13
herbal medicinal products	11 (3.0%)	10	1

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

According to an analysis of the status of prescription drugs and OTC drugs from finished drugs, prescription drugs accounted for were 74.0% (1,514 items) about 2.8 times more than OTC drugs of 26.0% (532 items) (Refer to Table 10).

In addition, in case of finished drugs, 96.9% (1,307 items) was prescription drugs while the prescription drugs (29.7%, 207 items) were less than the OTC drugs (70.3%, 490 items) in terms of the number of notified items.

Table 10. Summary of Drug Approval Status in 2018

(Unit: number of items)

Item	Total	Prescribed	OTC
Finished	2,046 (100%)	1,514 (74.0%)	532 (26.0%)

Approved	1,349 (100%)	1,307 (96.9%)	42 (3.1%)
Declared	697 (100%)	207 (29.7%)	490 (70.3%)

* Excluding drugs for export only, including revoked and withdrawn items

According to a detailed analysis of annul trends of approved and notified items, the number of prescription drugs in 2018 was 1,514 items, decreased by 3.8% from 1,573 items in 2017, but the number of OTC drugs was 532 items in 2018 increased by 11.8% from 476 items in 2017 (Refer to Table 11).

The approval and notification cases of drug substances have decreased for recent years, but increased to 75 items in 2018. In addition, the cases of notification of herbal substances in 2018 were 361 items, ~~which~~ decreased by 14.0% (59 items) from 420 items in 2017.

There are differences in increase and decrease by drug types, but the cases of items approved and notified in 2018 were similar to those of 2017 (Refer to Figure 2 and Table 11).

Table 11. Number of Approvals (Notification) by Drug Type (2012-2018)

(Including Revoked and Withdrawn Items)

(Unit: number of items)

Item	2012	2013	2014	2015	2016	2017	2018
Prescription drugs	1,002	1,669	2,090	2,289	2,280	1,573	1,514
(Increase YoY, %)		66.6%	25.2%	9.5%	-0.4%	-31.0%	-3.8%
OTC	406	427	726	626	481	476	532
(Increase YoY, %)		5.2%	70.0%	-13.8%	-23.2%	-1.0%	11.8%
Drug substances	110	114	113	99	84	55	75
(Increase YoY, %)		3.6%	- 0.9%	-12.4%	-15.2%	-34.5%	36.4%
herbal substances	3,215	186	178	1,909	983	420	361
(Increase YoY, %)		- 94.2%	- 4.3%	972.5%	-48.5%	-57.3%	-14.0%
Total	4,733	2,396	3,107	4,923	3,828	2,524	**2.482**

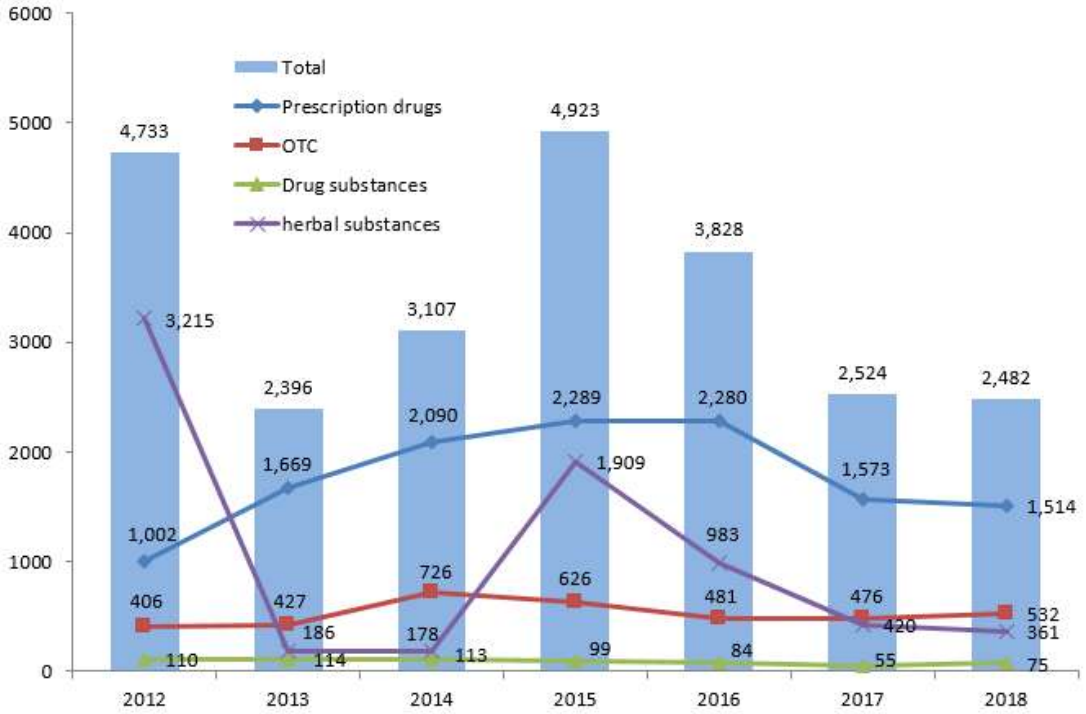


Figure 2. Information on Approval of Drugs by Drug Type (2012~2018)

1.2 Approval of New Drugs

New drugs newly approved in 2018 are 15 items in total including 11 chemical drugs (2 MF item and 9 imported items) and 4 biopharmaceuticals (4 imported items). For the number of ingredients in those new drugs, 12 new ingredients were approved including 8 ingredients from chemical drugs and 4 ingredients from biopharmaceuticals (Refer to Table 12 and, for the total list of new drugs, Refer to Table 15).

It was found that 86.7% of new drugs were imported items showing imported items still took most of new drugs.

Table 12. New Drug Approvals in 2018

(Unit: number of items)

Item	Total [No. of Ingredients]	Chemical drugs	Biopharmaceuticals	Herbal medicinal products
	15 [1] (100%) [12]	11 [2] [8]	4 [3] [4]	0 [0]

Manufactured	2 (13.3%) [2]	2 [2]	0	0
Imported	13 (86.7%) [10]	9 [6]	4 [4]	0

1) Of the 15 items, 4 items that are both orphan drug and new drug

According to the approvals on new drugs since 2010, the number of items decreased from 2010 to 2012 and increased from 2013 to 2014 and tended to decrease again since 2015–(Refer to Table 13 and Figure 3).

When it comes to the ratio of imported items to the new drugs since 2010, the imported items were 88.2% and the manufactured items were 11.8%, which show introduction of imported new drugs to the country most affected the number of new drugs. In addition, as for new drugs domestically developed and approved since 2010, 1-2 items were approved steadily each year excluding 2015 (5 items) and 2 items were approved in 2018.

Ministry of Food and Drug Safety(MFDS) has "Expedited Review" system for the medical products requiring urgent domestic development/ approval or introduction under which the part of data is allowed to be submitted after market release or provides a priority review. The subjects of expedited reviews include ▲ drugs that can expect therapeutic effects against life-threatening or severe diseases such as AIDS and cancer ▲ drugs that are not considered to be treatable by existing therapies due to tolerance, so prompt introduction is considered to be required ▲ drugs that can be expected to prevent or treat bioterrorism infectious diseases and other infectious diseases and ▲ orphan drugs.

In addition, the Ministry of Food and Drug Safety operates the PHARM NAVI Program (chemical drugs) and Majungmul(priming water) Project (Biopharmaceuticals) to reduce trials and errors of domestic pharmaceutical companies in the application process of medical product approval and promote the fast commercialization linkage. Through these projects, the Ministry provides information on approval review and supports operation of training programs (holding seminars), and customized consultation for each pharmaceutical item and so on.
MFDS will continue to do its utmost efforts to support the development of therapeutic drugs for life-threatening diseases and to secure public health.

Table 13-1. Approval of Chemical, Biopharmaceuticals and Herbal Medicinal Products as New Drugs by Year (2010-2018) (Including Revoked and Withdrawn Items)

(Unit: number of items)

Item	2010	2011	2012	2013	2014	2015	2016	2017	2018

No. of approved items [1] (No. of new drug ingredient)		49 (26)	31 (22)	17 (14)	23 (15)	49 (27)	34 (19)	25 (10)	29 (18)	15 (12)
Chemical drug	Domestically developed drugs [2]	1	2	2	1	1	5	1	1	2
	Manufactued[3]	3	8	3	3	3	6	2	1	2
	Imported	43	17	10	13	38	18	19	16	9
Biopharmaceuticals	Domestically developed drugs [2]	0	0	0	0	0	0	0	1	0
	Manufactured	0	0	0	0	0	0	0	1	0
	Imported	1	6	4	6	8	10	4	11	4
herbal medicinal products Formulation	Manufactured	0	0	0	0	0	0	0	0	0
	Imported	2	0	0	1	0	0	0	0	0

1) Number of new drugs approved in the year excluding items designated as new drugs due to removal from the orphan drugs designations

2) In the case of domestically developed new drugs, items with several contents were indicated as one item,

3) The number of products manufactured and marketed include that of domestically developed drugs.

Table 13-2. New Drug Approval Status by Year (2010~2018) (Including Revoked and Withdrawn Items)

(Unit: number of items)

Item	2010	2011	2012	2013	2014	2015	2016	2017	2018
Manufactured (11.8%)	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%)
Imported (88.2%)	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%)
No. of items	49	31	17	23	49	34	25	29	15

According to an analysis of the new drugs approved since 2010 by therapeutic class, 19 items of nervous system agents in 2010, 6 items of Urogenital organ agents (3 ingredients) in 2011, 6 items of antineoplastic tumors (4 ingredients) in 2012, 6 items of Antidiabetic agents (3 ingredients) in 2013, 16 items of nervous system agents (5 ingredients) in 2014, nervous system agents (8 items) and antidiabetic agents (8 items) in 2015, 14 items of antineoplastic agents (7 ingredients) in 2016, 11 antineoplastic agents (5 ingredients) in 2017 and 4 items of miscellaneous chemotherapeutics (2 components) in 2018 took the largest ratio respectively.

Over the past 9 years, the cumulative approval cases of new drugs by drug classification code were anti-neoplastic agents (58 items), nervous system agents (47 items), and antidiabetic agents (30 items) in the descending order (Refer to Table 14).

Table 14. Therapeutic Class of New Drug Approvals by Year (2010-2018) (Including Revoked, Withdrawn and Released Orphan Items)

(Unit: number of items)

Item	2010	2011	2012	2013	2014	2015	2016	2017	2018	Total
nervous system agents	19	0	1	1	16	8	2	0	0	47
Antineoplastic agents	8	3	6	4	7	5	14	11	1	59
Antidiabetic agents	1	3	1	6	11	8	0	0	2	32
Antiviral agents	7	1	1	0	2	5	2	3	0	21
Cardiovascular agents	5	3	0	0	1	2	6	9	1	27
Respiratory organ agents	3	1	0	0	4	1	2	1	0	12
Urogenital organ agents	0	6	0	2	0	0	0	0	0	8
Sensory organ agents	1	1	2	0	3	0	0	0	0	7
Allergic agents	0	1	2	3	1	0	0	8	2	17
Others	5	12	4	7	4	9	6	3	9	59
Total	**49**	**31**	**17**	**23**	**49**	**38**	**32**	**35**	**15**	289

Figure 3. Approval Status of New Drugs by Year (2010 - 2018)
(Including Revoked, Withdrawal and Released New Drugs) (Refer to Table 15)

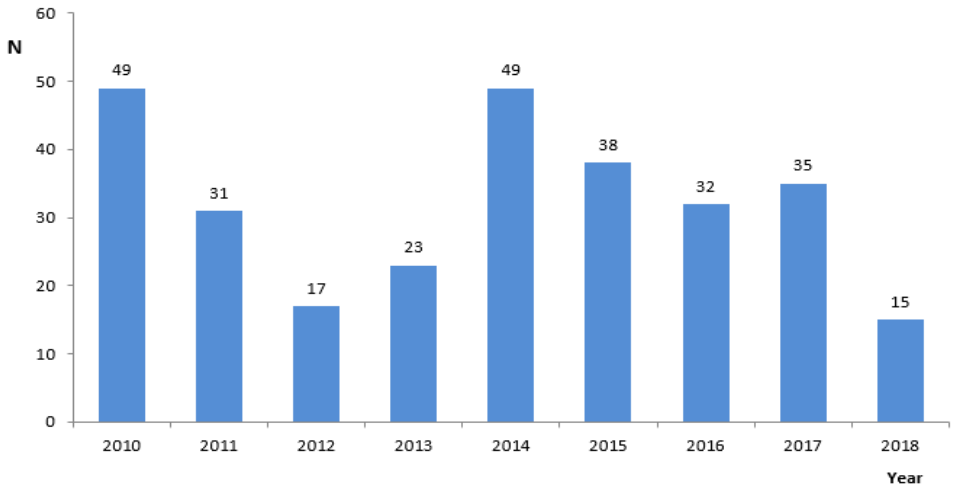


Table 15. 2018 New Drug Approval List (Including New Drugs Removed from Orphan Drug List)

□ Chemicals, □ Biopharmaceuticals

No.	Manufactured./ Imported	Product Name	Company name	Approval Date	Code	Efficacy and effectiveness (some omitted)
1	Import	Maviret tablet	Abbvie Korea	2018-01-12	[629] Miscellaneous Chemotherapeutics	treatment of adult patients with chronic hepatitis C virus(HCV) genotype 1, 2, 3, 4, 5, or 6 infection
2	Mfg.	Alzavue Injectinon(Florapronol(18F))	FutureChem Co., Ltd.	2018-02-02	[431] Radioactive medicines	It is used for positron emission tomography(PET) imaging of the brain to estimate β-amyloid neuritic plaque density in adult patients with cognitive impairement who are being evaluated for Alzheimer's disease(AD) or other causes of cognitive decline
3	Import	Velphoro chewable tablet(sucroferric oxyhydroxide).	Fresenious Medical Care Korea	2018-03-20	[219] Miscellaneous Cardiovascular agents	control of serum phosphorus levels in chronic kidney disease(CKD) patients on haemodialysis(HD) or peritoneal dialysis(PD)
4	Import	Dupixent prefilled syringe 300mg (dupilumab,recombinant)	Sanofi-aventis Korea Co., Ltd.	2018-03-30	[142] Non-specific Immuno suppressants	treatment of adult patients with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. DUPIXENT can be used with or without topical therapy.
5	Import	Tremfya Pre-filled Syringe (guselkumab,recombinant)	Janssen Korea Ltd.	2018-04-12	[142] Non-specific Immuno suppressants	Plaque psoriasis Indicated for treatment of adult patients with moderate to severe psoriasis who are candidates for phototherapy or systemic

						therapy.
6	Import	Octenisept solution	BL & H Co., Ltd	2018-04-30	[261] Antimicrobial agents	- antiseptic treatment in the ano-genital region(including the vagina, vulva and glans penis) prior to diagnostic, surgical procedure and bladder catehterization - short-term antiseptic treatment of small wound
7	Import	Akynzeo capsule	CJ Healthcare Corp.	2018-06-28	[235] Emetics, antiemetics	adult 1. Prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy 2. Prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy
8	Mfg.	K-CAP tablet 50mg(tegoprazan)	CJ Healthcare Corp.	2018-07-05	[232] Peptic ulcer agents	1. treatment of erosive gasroesophageal reflux disease(GERD) 2. treatment of non-erosive gasroesophageal reflux disease(GERD)
9	Import	Steglatro tablet 5mg(ertugliflozin L-pyroglutamic acid)	MSD Korea Ltd	2018-08-17	[396] Antidiabetic agents	adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus
10	Import	Steglatro tablet 15mg(ertugliflozin L-pyroglutamic acid)				
11	Import	Gattex Injection (teduglutide)	Shire Pharma Korea Co., Ltd.	2018-08-17	[239] Miscellaneous digestive organ agents	treatment of patients aged 1 year and above with Short Bowel Syndrome who are dependent on parenteral support.

12	Import	Imfinzi Injection (Durvalumab)	Astra Zeneca Korea	2018-12-04	[421] Antineoplastic agents	treatment of patients with locally advanced, unresectable non-small cell lung cancer whose disease has not progressed following concurrent platinum-based chemoradiation therapy
13	Import	Prevymis injection(letermovir)	MSD Korea Ltd	2018-12-26	[629] Miscellaneous Chemotherapeutics	prophylaxis of cytomegalovirus (CMV) infection and disease in adult CMV seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT)
14	Import	Prevymis tablet 480mg(letermovir)				
15	Import	Prevymis tablet 240mg(letermovir)				

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

Table 16. List of New Drugs Developed in Korea (1999-2018) (Including Revoked/Withdrawn Items)

No.	product name	Company Name	Active ingredient	Efficacy/ Effectiveness	Remarks
1	Sunpla Injection	SK Chemicals	Heptaplatin	Anticancer drug (stomach cancer)	1999.7.15 (1993.7.20)
2	Easyf Solution 0.005%	DAEWOONG PHARMACEUTICAL	Recombinant human epidermal growth factor	Diabetic, foot ulcer treatment	2001.5.30 (1997.3.4)
3	Milican Injection	DONG WHA PHARM.	Holmium nitrate- 166	Anticancer drug (liver cancer)	2001.7.6 (1997.5.28)
4	Q-ROXIN Tablet	JW Pharmaceutical	Balrofloxacin	Antimicrobial agent (antibiotic)	2001.12.17 (1993.5.6)
5	Factive Tablet	LG Chemical .	Gemifloxacin Mesylate	Antimicrobial agent (antibiotic)	2002.12.27 US FDA approval (2003.4.4)
6	Apitoxin Injection	Guju Pharmaceutical	Dry honey bee poison	Arthritis treatment	2003.5.3 (1999.11.29)
7	Pseudovaccine Injection	CJ Healthcare	Dried pseudomonas protein	Pseudomonas preventive vaccine	2003.5.28 (1995.1.26)
8	Camtobell	Chong Kun Dang	Belotecan	Anticancer drug	2003.10.22

	Injection	Pharm.			
9	Revanex Tablet	Yuhan Corporation	Revaprazan HCl	Anti-ulcer agent	2005.9.15
10	Zydena Tablet	DONG-A ST	Udenafil	Erectile dysfunction treatment agent	2005.11.29
11	LEVOVIR Capsule	Bukwang Pharm.	Clevudine	Hepatitis B treatment agent	2006.11.13 (2001.06.13)
12	PELUBI Tablet	Daewon Pharmaceutical	Felubiprofen	Osteoarthritis treatment agent	2007.4.20
13	MVIX Tablet	SK Chemicals	Mirodenafil HCl	Erectile dysfunction treatment agent	2007.7.18
14	Noltec Tablet	IL-YANG PHARM.	Ilaprazole	Anti-ulcer agent	2008.10.28
15	Kanarb Tablets	Boryung Pharmaceutical	Fimasartan potassium trihydrate	Antihypertensive agent	2010.9.9
16	PYRAMAX Tablet	SHINPOONG Pharmaceutical Co.	Pyronaridine tetraphosphate, Artesunate	Malaria treatment agent	2011.8.17
17	ZEPEED Tablet	JW Pharmaceutical	Avanafil	Erectile dysfunction treatment agent	2011.8.17
18	Supect Capsule	IL-YANG PHARM.	Radotinib HCl	Cancer drug (leukemia)	2012.1.5
19	Zemiglo Tablet	LG Chemical	Gemigliptin tartrate sesquihydrate	Diabetes treatment agent	2012.6.27
20	Duvie Tablet	Chong Kun Dang Pharm.	Lobeglitazone sulfate	Diabetes treatment agent	2013.7.4
21	Riavax Injection	KAEL GEMVAX	Tertomoride hydrochloride	Anticancer drug	2014.9.15
22	Acelex Capsule	CrystalGenomics Inc.	Polmacoxib	Osteoarthritis treatment agent	2015.2.5
23	ZABOLANTE Tablets	DONG WHA PHARM.	Zabo flocasin D-Aspartate hydrate	Antimicrobial agent (antibiotic)	2015.3.20
24	Sivextro Tablet	DONG-A ST	Teddyolide phosphate	Antimicrobial agent (antibiotic)	2015.4.17
25	Sivextro Injection	DONG-A ST	Teddyolide phosphate	Antimicrobial agent (antibiotic)	2015.4.17
26	Suganon Tablet	DONG-A ST	Evogliptin tartrate	Diabetes treatment agent	2015.10.2

27	Olita Tablet	Hanmi Pharmaceutical	Olmutinib dihydrochloride monohydrate	Anticancer drug	2016.5.13
28	BESIVO TABLET	ILDONG PHARMACEUTICAL CO.	Bexifovir dipiviris Maleate	Hepatitis B treatment agent	2017.5.15
29	Invossa-K Injection	Kolon Life Science	allogeneic cartilage derived chondrocyte, TGF-beta1 transduced allogeneic cartilage derived chondrocyte	Osteoarthritis treatment agent	2017.7.12
30	Alzavue Inj.	FutureChem Co., Ltd	Florapronol(18F)	radioactive diagnostic agent for AD	2018.2.2
31	K-CAP Tab.	CJ Health Care Corp.	Tegoprazan	GERD treatment agent	2018.7.5

1.3 Approval on orphan drugs

Orphan drugs approved in 2018 were 17 items in total (including 4 orphan new drugs) consisting of 6 manufacturing items and 11 import item and 14 items of chemical drugs, 2 items of biopharmaceuticals and 1 herbal medicine item.

For the number of ingredients, 9 ingredients were approved including 6 ingredients of chemical drugs, 2 ingredients of biopharmaceuticals and 1 ingredients of herbal medicinal products (Refer to Table 17).

Table 17. Orphan Drug Approval Status in 2018

(Unit: number of items)

Item	Total (No. of ingredients)	Chemical drug	Biopharmaceuticals	Herbal medicinal products
Imported	17 (9)	14 (6)	2 (2)	1 (1)
Orphan new drugs	4 (2)	3 (1)	1 (1)	0

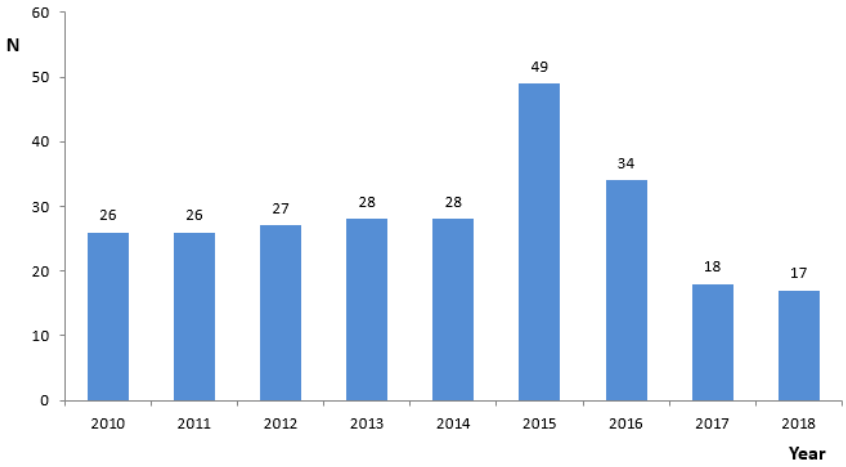
According to orphan drug approvals since 2010, the number of items approved was similar until 2014, but 49 items were approved in 2015, which is 1.8 times larger than the annual average of approved items for the recent 5 years (27 items). This seems to be an outcome of conducting of prior GMP program evaluation, review of specifications and test methods, and submission of risk management plan for orphan drugs since July 2015 (Table 18, Figure 4)., From 2016, the approval of orphan drugs tends to decrease and 18 items and 17 items were approved in 2017 and 2018 respectively.

Table 18. Approval of New Orphan Drugs by Year (2010~2018)
(Including Revoked/Withdrawn Items)

(Unit: number of items)

Item	2010	2011	2012	2013	2014	2015	2016	2017	2018
Orphan drugs	26	26	27	28	28	49	34	18	**17**

Figure 4. Status of Approval of Orphan Drugs (2010-2018)



*17 items in total including orphan new drugs in 2018

In addition, a total of 16 ingredients were designated as orphan drugs in 2018 (Refer to Table 19).

Table 19. Ingredients of Newly Designated Orphan Drugs in 2018

No.	Ingredient	Target disease	Remarks
1	idebenone(oral)	Leber Hereditary Optic Neuropathy (LHON)	
2	midostaurin(oral)	1. in combination with standard induction and consolidation chemotherapy for patients with newly diagnosed 릿3 mutation postitive acute myeloid leukemia (AML) 2. aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL)	

3	letermovir(oral, injection)	prophylaxis of cytomegalovirus (CMV) infection and disease in adult CMV seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT)	
4	brigatinib(oral)	treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer(NSCLC) previously treated with ALK inhibitor	
5	cladribine(oral)	treatment of relapsing-remitting multiple sclerosis	
6	niraparib(oral)	monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed ovarian, fallopian tube, or primary peritorial cancer who are in response to platinum-based chemotherapy	
7	Emicizumab(injection)	Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in patients with hemophilia A (congenital factor VIII deficiency) with factor VIII inhibitors.	
8	Recombinant human parathyroid hormone(injection)	adjuvant treatment of hypoparathyroidism who cannot be adequately controlled standard therapy alone	
9	Burosumab(injection)	FGF23 related hypophosphatemic rickets･osteomalacia	
10	Venetoclax(oral)	monotherapy for chronic lyphocytic leukemia patients who are unsuitable for or have failed both chemoimmunotherapy and a B-cell receptor pathway inhibitor	
11	Osilodrostat(oral)	treatment of endogeneous cushing's syndrome in adults	
12	Pitolisant(oral)	treatment of narcolepsy with or without cataplexy in adults	
13	Pegvisomant(injection)	treatment of adult patients with acromegaly who have an inadequate response to surgery and/or radiation therapy and in whom an appropriate medical treatment with somatostatin analogues did not normalize IGF-I concentrations or who not tolerated. The goal of treatment is to normalize serum IGF-I levels	

14	Ravulizumab(injection)	paroxysmal nocturnal hemoglobinuria (PNH)	
15	Lanadelumab(injection)	prophylaxis to prevent attacks of hereditary angioedema (HAE) in patients 12 years and older	
16	recombinant adeno-associated virus serotype 9 (AAV9) containing the human survival motor neuron (SMN) gene / 2.0 X 10^{13} ~ 6.0 X 10^{13} vector genome (Vg) (injection)	Spinal muscular atrophy (Type 1)	

1.4 Drug approval/notification status by main therapeutic class

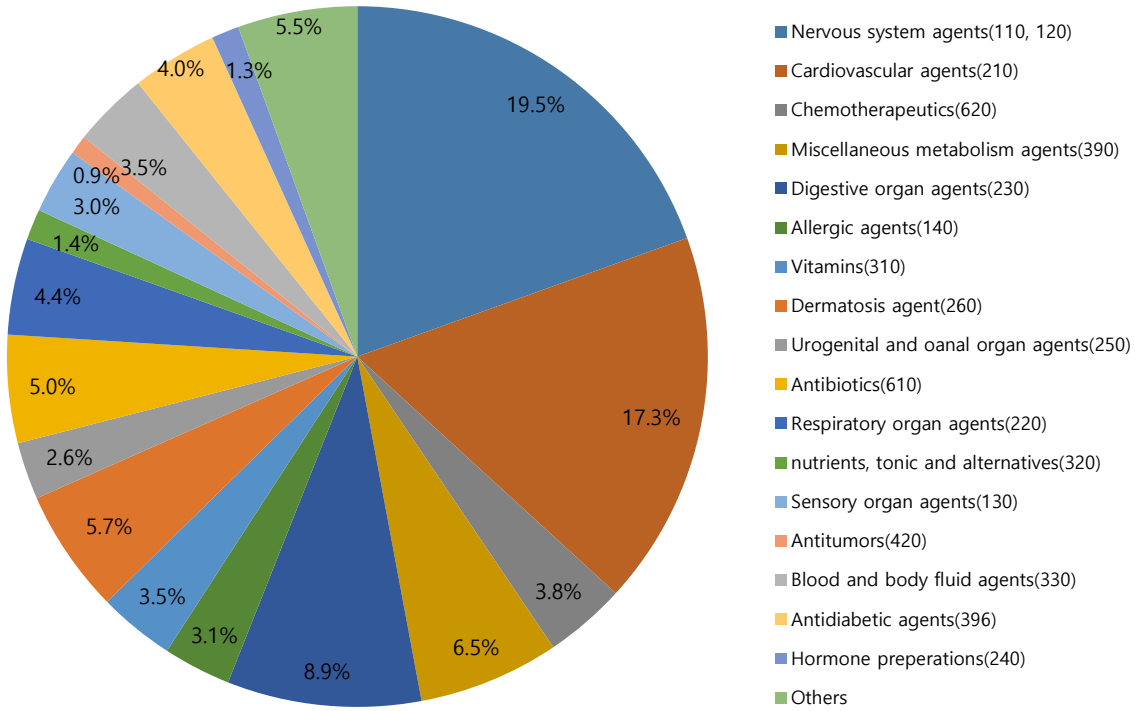
According to the approval and notification of finished drugs in 2018 by efficacy, there were drugs for nervous system (19.5%), circulatory drugs (17.3%), metabolic drugs (10.5%), digestive system drugs (8.9%), and dermatologic drugs (5.7%) in descending order (Refer to Table 20 and Figure 5)

Table 20. Number of Approved and Notified Items by therapeutic class in 2018 (Including Revoked and Withdrawn Items)

(Unit: number of items)

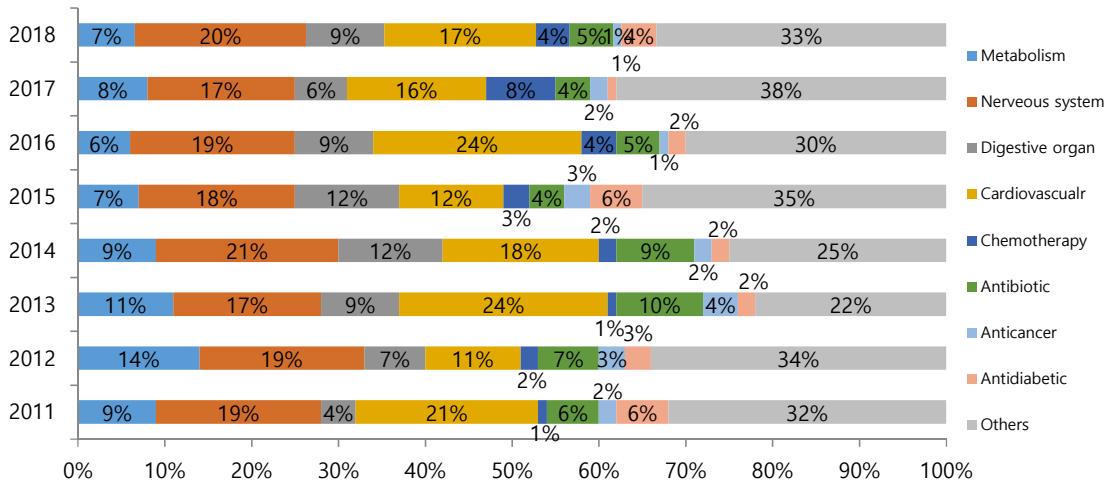
Class no. / Total	Nervous system (110, 120)	Circulatory system (210)	Metabolism (390)		Digestive system (230)	Dermatologic (260)	Antibiotic drugs (610)	Respiratory organs (220)	Chemo therapy (620)	Others
			Others	Diabetes (396)						
2,046	399 (19.5%)	354 (17.3%)	133 (6.5%)	81 (4.0%)	183 (8.9%)	117 (5.7%)	102 (5.0%)	91 (4.4%)	77 (3.8%)	566 (27.7%)
			214(10.5%)							

Figure 5. Ratio of Approval Cases (Notification) Classified by Major Efficacy Groups in 2018 (Including Revoked and Withdrawn Items)



As for the approvals and notifications by therapeutic class since 2011, metabolic drugs, nervous system drugs, digestive system drugs and circulatory drugs take large part as in the previous year. In 2018, nervous system drugs which took the largest ratio as in the previous year increased by 3% YoY. Most of the nervous system drugs (70%) were Antipyretics/analgesic/anti-inflammatory drugs and miscellaneous central nervous system agents. The drugs which took the second largest ratio were cardiovascular agents, most of which (98.6%) were antihypertensives, hyperlipidemia agents and miscellaneous cardiovascular agents (Refer to Figure 6 and Table 22).

Figure 6. Annual Approval (Notification) of Drugs by Drug Therapeutic Class (2011-2018)



According to detailed approvals and notifications by drug classification code for sub-therapeutic class, antipyretic/analgesic/anti-inflammatory agents (code 114) and antihypertensives (code 214) took 7.4% (152 items) and 7.1% (145 items) respectively and they have remained top 5 for recent 5 years. Besides, miscellaneous central nervous system agents (6.3%, 128 items) and hyperlipidemia agents (5.7%, 117 items) ranked high (Refer to Table 21).

Table 21. Single Classification Number of Top 5 Approval Items (2015~2018)
(Including Revoked/Withdrawal Items)

	2015		2016		2017		2018	
	Efficacy classification (code number)	**No. of items**	**Efficacy classification (code number)**	**No. of items**	**Efficacy classification (code number)**	**No. of items**	**Efficacy classification (code number)**	**No. of items**
1	Miscellaneous Urogenital and anal organ agents(259)	315 (10.8%)	Antihypertensives (214)	366 (13.3%)	Miscellaneous chemotherapeutics (629)	166 (8.1%)	Antipyretic/analgesic/ anti-inflammatory agents (114)	152 (7.4%)
2	Antipyretic/analgesic/anti-inflammatory agent (114)	261 (9.0%)	Hyperlipidemia agent (218)	227 (8.2%)	Antipyretic/analgesic/ anti-inflammatory agents (114)	146 (7.1%)	Antihypertensives (214)	145 (7.1%)
3	Peptic ulcer agent (232)	237 (8.1%)	Miscellaneous central nervous system drugs (119)	177 (6.4%)	Antihypertensives (214)	138 (6.7%)	Miscellaneous central nervous system drugs (119)	128 (6.7%)
4	Antidiabetic agent (396)	180 (6.2%)	Antipyretic/analgesic/ anti-inflammatory agents (114)	173 (6.3%)	Miscellaneous central nervous system drugs (119)	112 (5.5%)	hyperlipidemia agents (218)	112 (5.5%)
5	Antihypertensives (214)	175 (6.0%)	Peptic ulcer agents (232)	153 (5.5%)	Miscellaneous metabolism agents (399)	112 (5.5%)	Miscellaneous metabolism agents (399)	112 (5.5%)
	No. of finished drugs approved and notified in 2015	2,915 (100%)	No. of finished drugs approved and notified in 2016	2,761 (100%)	No. of finished drugs approved and notified in 2017	2,049 (100%)	No. of finished drugs approved and notified in 2018	2,046 (100%)

Table 22. Approval and Notification of Finished Drugs by Major Therapeutic Class in 2018

Classification	Drug classification code		No. of items
Nervous system drug	111	General anesthetics	3
	112	Hypnotics, and sedatives, anxiolytics	3
	113	Antiepileptics	36
	114	Antipyretics and analgesics, anti-inflammatory agents	152

	116	Anti-vertigo agents	3
	117	Psychotropics	60
	119	Miscellaneous central nervous system agents	128
	121	Local anesthetics	6
	122	Skeletal muscle relaxants	3
	123	Autonomic nervous system agents	2
	124	Antispasmodics	3
	Subtotal		399
Ophthalmology and ENT	131	Ophthalmic agents	47
	132	Otic and nasal agents	15
	Subtotal		62
Cardiovascular drugs and blood and body fluid agents	212	Antiarrhythmic agents	1
	214	Antihypertensives	145
	215	Capillary stabilizer	3
	217	Vasodilators	1
	218	Hyperlipidemia agents	117
	219	Miscellaneous Cardiovascular agents	87
	331	Blood substitutes	1
	332	Hemostatics	1
	333	Anticoagulants	47
	339	Miscellaneous blood and body fluid agents	22
	Subtotal		425
Respiratory organs and Allergy drug	141	Antihistamines	37
	142	Non-specific immunogen preparations	10
	149	Miscellaneous allergic agents	17
	222	Antitussive expectorants	52
	223	Inhalation treatment preparations	24
	229	Miscellaneous respiratory organ agents	15
	Subtotal		155
Digestive tract drug	231	Dental and oral agents	13
	232	Peptic ulcer agents	82
	233	Stomachics and digestives	9
	234	Antacids	14
	235	Emetics, antiemetics	10
	237	Intestinal drugs	14
	238	Purgatives, clysters	13

	239	Miscellaneous digestive organ agents	28
	Subtotal		183
Urinary and reproductive system drug	253	Emmenagogue	1
	254	Contraceptives	4
	256	Hemorrhoidal preparations	4
	259	Miscellaneous urogenital and anal organ agents	45
	Subtotal		54
Metabolic drug	311	Vitamin A and D preparations	3
	313	Vitamin B preparations (excluding vitamin B1)	7
	315	Vitamin E and K preparations	1
	316	Multivitamins preparations	4
	319	Miscellaneous vitamins	57
	321	Calcium preparations	8
	322	Mineral preparations	4
	325	Protein and amino acid preparations	9
	329	Miscellaneous ~~nourishing~~ nutrients, tonic and alternatives	8
	391	Liver disease agents	25
	392	Antidotes	2
	394	Gout preparations	3
	395	Enzyme preparations	1
	399	Miscellaneous metabolism agents	102
	Subtotal		234
Antidiabetic drug	396	Antidiabetic agents	81
	Subtotal		81
Anticancer drug	421	Antineoplastic agents	13
	429	Miscellaneous antitumors	5
	Subtotal		18
Antibiotics	611	Acting mainly acting on gram-positive bacteria	3
	612	Acting mainly acting on gram-negative bacteria	2
	614	Acting mainly acting on gram-positive germ, rickettsia, and virus	7
	615	Acting mainly acting on gram-negative germ, rickettsia, and virus	3
	618	Acting mainly acting on gram-positive and gram-negative bacteria	71
	619	Miscellaneous antibiotic agents (including complex antibiotic	16

		agents)	
	Subtotal		102
Chemotherapeutic agent	625	Furan complex preparations	1
	629	Miscellaneous Chemotherapeutics	76
	Subtotal		77
Others (classification that does not belong to the above efficacy group)			256
Total			2,046

2. Information on Approval of Drugs (Chemical Drugs)

2. Information on Approval of Drugs (Chemical Drugs)

The number of chemical drugs approved in 2018 by review type is as follows: new drugs (11), orphan drugs (14), drugs requiring data submissions (239 including 6 incrementally modified drugs), and drug substances (8) items. From drugs requiring data submissions (239 items), drugs with new composition took the largest, accounting for 46.4% (111 items), followed by drugs with new salts (29.3%, 70 items) and, drugs with new formulation (same route of administration) (15.1%, 36 items) (Refer to Table 23).

The number of new drugs approved in 2018 was 11 items decreased by 35% from 17 items in 2017 (excluding those removed from orphan drug designation) and, out of them, 9 items (81.8%) were imported items (Refer to Table 24). The number of incrementally modified drugs was 6 items, decreased from 18 in 2015, 24 in 2016 and 11 in 2017 (Refer to Table 28).

For the success of drug development, commercialization and advancement into the global market, MFDS has promoted the "PHARM NAVI" project from 2014 and also provided the consultation service and held the product briefing to provide advice on approval/review during the product development. Besides, MFDS has established and revised guidelines and guides for implementation of ICH guidelines to strengthen global competitiveness of the domestic pharmaceutical industries.

Also, MFDS continuously holds training workshops to support drug developers and held ICH guideline training (November) and a comprehensive briefing session on drug review/ approval (May). In addition, MFDS has launched "Pharm. Together", the private/government communication channel to strengthen communication with industries and actively handle the complaints related with approval/review since July 2018.

Table 23. Approval Status of Pharmaceutical Drugs (Chemical Drugs) by Review Type in 2018

<table>
<tr><th>Type</th><th colspan="5">Review type</th><th colspan="2">No. of approved items</th></tr>
<tr><td>1</td><td rowspan="2">New drugs (11)</td><td colspan="2">New drugs</td><td></td><td colspan="2">8</td></tr>
<tr><td>2</td><td colspan="2">Orphan new drugs</td><td rowspan="2">Orphan drugs (14)</td><td colspan="2">3</td></tr>
<tr><td>3</td><td></td><td colspan="2">Orphan drugs</td><td colspan="2">11</td></tr>
<tr><td>4</td><td colspan="4">Drugs requiring data submission</td><td colspan="2">239</td></tr>
<tr><td>4-1</td><td colspan="2">Incrementally modified new drug</td><td colspan="3">New dosage form (same route of administration)</td><td colspan="2">6</td></tr>
<tr><td>4-2</td><td rowspan="3">Drugs requiring data submission</td><td colspan="3">New salts or isomers</td><td rowspan="3">233</td><td>70</td></tr>
<tr><td>4-3</td><td colspan="3">New composition</td><td>111</td></tr>
<tr><td>4-4</td><td colspan="3">Change in strength</td><td>16</td></tr>
</table>

4-5		New route of administration		3
4-6		New administration/dosage		3
4-7		New dosage form (same route of administration)		30
5	Drug substance			38

2.1. Information on Approval of new drugs

The number of new drugs approved in 2018 is 11 items (2 manufactured and 9 imported), down by 47.6% YoY, and the top classification code of approved items is in the order of other chemotherapy drugs (4 items) and diabetic drugs (2 items) (Refer to Tables 24-26).

Table 24. Approval Status of Manufactured/Imported New Drugs (2014-2018) (Chemical Drugs)

(Unit: number of items)

	2014	2015	2016	2017	2018
Manufactured	3	6	2	1	2
Imported	38	22	22	20	9
Total	41 [1)]	28 [2)]	24 [3)]	21 [4)]	11 [5)]
YoY Growth (%)	-31.7%	-14.3%	-12.5%	-47.6%	

1) Including 1 drug removed from the orphan drug list: (Removed from the orphan drug list) Symbenda Injection

2) Including 1 drug removed from the orphan drug list in 2015:
(Removed from the orphan drug list) Xtandi Soft Capsule 40mg, Volibris Tablet 5mg, 10mg and Zytiga Tablet 250mg

3) Including 4 items designated as both new drug and orphan drug, and 3 items removed from the orphan drug list in 2016:
(New orphan drugs) Tecfidera Capsule 120, 240mg and Ofev Soft Capsule 100, 150mg,
(Removed from the orphan drug list) Jakavi Tablet 5, 15, 20mg

4) Including 4 items removed from the orphan drug list in 2017: Refer to Table 26
(Removed from the orphan drug list) Pomalyst capsule 1, 2, 3, 4 mg

5) Including 3 items which were approved as both new drug and orphan drug in 2018:
(Orphan new drug) Prevymis Inj., Prevymis Tab. 240mg, 480mg

Table 25. Approval Status of New Drugs by Drug Classification Code (2014-2018) (Chemical Drugs)

(Unit: number of items)

	Nervous system	Circulatory system	Respiratory	Blood Coagulation inhibitor	Diabetes	Antivirus	Anti neoplastic	Antibiotic matter	Allergy	Sensory organ	Liver disease	Radiological diagnosis	Anti-hormone drug	Outer skin	Digestive organs	Chemotherapy	Total
2014	16	1	4	0	8	2	5	0	1	2	1	1	0	0	0	0	41
2015	8	2	1	3	2	5	4	2	0	0	0	1	0	0	0	0	28
2016	2	6	2	0	0	2	9	0	0	0	0	0	3	0	0	0	24
2017	0	3	0	0	0	2	9	1	4	0	1	0	0	1	0	0	21
2018	0	1	0	0	2	0	0	0	0	0	0	1	0	1	2	4	11

There was no noticeable feature in new drug approval in 2018, but it was confirmed that the hepatitis C virus drug of which approval of new drugs were rare have been introduced to the domestic market every year since 2015. (2015: Asunaprevir, Daclatasvir, Sofosbuvir, Sofosbuvir/ Ledipasvir; 2016: Elbasvir/ Grazoprevir; and 2017: Dasabuvir, Ombitasvir/ Paritaprevir/ Ritonavir).

In 2018, 4 items of other chemotherapy agents (1 item for chronic C type and 3 items for CMV action), 2 items for diabetes (SGLT2 inhibitor), 1 item for regulator which is serum phosphorus for patients with chronic kidney disease, 1 item of sanitizer/ disinfectant for outer skin, 1 item for agent for preventing nausea and vomiting due to chemotherapy drugs, 1 item for peptic ulcer, and 1 item for radiopharmaceutical were approved

The product names, manufacturers, dates of approval, API, efficacy and effectiveness, mechanism of action for new drugs approved in 2018 in the sequential order of are as follows:

'Maviret tablet' (Abbvie Korea, approved in Jan. 12, 2018) is used for treatment of adult patients with chronic hepatitis C virus(HCV) genotype 1, 2, 3, 4, 5, or 6 infections. Maviret is a fixed-dose combination of two pan-genotypic, direct-acting antiviral agents, glecaprevir(NS3/4A protease inhibitor)/pibrentasvir(NS5A inhibitor), targeting multiple steps in the HCV viral lifecycle.

'Alzavue injection(Florapronol(18F))' (FutureChem Co., Ltd., Feb. 2, 2018) is a radioactive medicine indicated for positron emission tomography(PET) imaging of the brain to estimate β-amyloid neuritic plaque density in adult patients with cognitive impairment who are being evaluated for Alzheimer's disease(AD) or other causes of cognitive decline. Florapronol(18F) is a PET image tracer that binds to beta-amyloid plaques in the brain.

'Velphoro chewable tablet(sucroferric oxyhydroxide)' (Fresenious Medical Care Korea, approved in Mar 20, 2018) is used for the control of serum phosphorus levels in chronic kidney disease(CKD) patients on haemodialysis(HD) or peritoneal dialysis(PD). Velphoro contains a mixture of polynuclear iron(III)-oxyhydroxide(pn-FeOOH), sucrose, and starches. The active moiety is a polynuclear iron(III)-oxyhydroxide.

Phosphate binding takes place by ligand exchange between hydroxyl groups and/or water and the phosphate ions throughout the physiological pH range of the gastrointestinal tract. Serum phosphorus levels are reduced as a consequence of the reduced dietary phosphate absorption.

'Octenisept solution' (BL&H Co., Ltd, approved in April 30, 2018) is a combination drug of octenidine dihydrochloride/phenoxyethanol, antimicrobial agent for outer skin. Octenisept is used for 'antiseptic treatment in the ano-genital region(including the vagina, vulva and glans penis) prior to diagnostic, surgical procedure and bladder catehterization'and 'short-term antiseptic treatment of small wound'.

'Akynzeo capsule' (CJ Healthcare Corp., June 28, 2018) is a fixed combination of palonoestron/netupitant. Akynzeo is used for 1. Prevention of acute and delayed nausea and vomiting associated with initial and repetitive courses of highly emetogenic cancer chemotherapy 2. Prevention of acute and delayed nausea and vomiting associated with initial and repetitive courses of moderately emetogenic cancer chemotherapy in adults. Netupitant is a selective antagonist of human substance P/neurokinin 1(NK1) receptors. Palonosetron is a 5-HT3 receptor antagonist with a strong binding affinity. Chemotherapeutic substances produce nausea and vomiting by stimulating the release of serotonin and serotonin then activates 5-HT3 receptors located on vagal afferents to initiate the vomiting reflex. Delayed emesis has been associated with the activation of tachykinin family neurokinin 1 (NK1) receptors (broadly distributed in the central and peripheral nervous systems) by substance P, netupitant inhibits substance P meditated responses.

'K-CAP tablet 50mg(tegoprazan)' (CJ Healthcare Corp., July 5, 2018) is a peptic ulcer agent, is used for 1. treatment of erosive gastroesophageal reflux disease(GERD), 2. treatment of non-erosive gastroesophageal reflux disease(GERD). Tegoprazan is a potassium-competitive acid blocker(P-CAB), shows reversible inhibition of gastric of H+/K+-ATPase.

'Steglatro tablet5, 15mg(ertugliflozin L-pyroglutamic acid)' (MSD korea Ltd, Aug 17, 2018) is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Ertugliflozin L-pyroglutamic acid is a sodium glucose co-transporter 2(SGLT2) inhibitor, SGLT2 is the predominant transporter responsible for reabsorption of glucose from the glomerular filtrate back into the circulation. By inhibiting SGLT2, ertugliflozin reduces renal reabsorption of filtered glucose and lowers the renal threshold for glucose, and thereby increases urinary glucose excretion.

'PREVYMIS injection, tablet 240mg, 480mg(letermovir)' (December 26, 2018) is an antiviral drug, is indicated for prophylaxis of cytomegalovirus (CMV) infection and disease in adult CMV seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT). Letermovir inhibits the CMV DNA terminase complex which is required for viral DNA processing and packaging.

Table 26. Approval Status of New Drugs in 2018 (Chemical Drugs)

No.	Manufactured/ imported	Product name	Company	Approval Date	Code	Efficacy/effects
1	Import	Maviret tablet	Abbvie Korea	2018-01-12	[629] Miscellaneous Chemotherapeutics	treatment of adult patients with chronic hepatitis C virus(HCV) genotype 1, 2, 3, 4, 5, or 6 infection
2	Mfg.	Alzavue Injectinon(Florapronol(18F))	FutureChem Co., Ltd.	2018-02-02	[431] Radioactive medicines	It is used for positron emission tomography(PET) imaging of the brain to estimate β-amyloid neuritic plaque density in adult patients with cognitive impairement who are being evaluated for Alzheimer's disease(AD) or other causes of cognitive decline
3	Import	Velphoro chewable tablet(sucroferric oxyhydroxide).	Fresenious Medical Care Korea	2018-03-20	[219] Miscellaneous Cardiovascular agents	control of serum phosphorus levels in chronic kidney disease(CKD) patients on haemodialysis(HD) or peritoneal dialysis(PD)
4	Import	Octenisept solution	BL & H Co., Ltd	2018-04-30	[261] Antimicrobial agents	- antiseptic treatment in the ano-genital region (including the vagina, vulva and glans penis) prior to diagnostic, surgical procedure and bladder catehterization - short-term antiseptic treatment of small wound
5	Import	Akynzeo capsule	CJ Healthcare Corp.	2018-06-28	[235] Emetics, antiemetics	adult 1. Prevention of acute and delayed nausea and vomiting associated with initial and repetitive courses of highly emetogenic cancer chemotherapy 2. Prevention of acute and delayed nausea and vomiting associated with

						initial and repetitive courses of moderately emetogenic cancer chemotherapy
6	Mfg.	K-CAP tablet 50mg(tegoprazan)	CJ Healthcare Corp.	2018-07-05	[232] Peptic ulcer agents	1. treatment of erosive gasroesophageal reflux disease(GERD) 2. treatment of non-erosive gasroesophageal reflux disease(GERD)
7	Import	Steglatro tablet 5mg(ertugliflozin L-pyroglutamic acid)	MSD Korea Ltd	2018-08-17	[396] Antidiabetic agents	adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus
8	Import	Steglatro tablet 15mg(ertugliflozin L-pyroglutamic acid)				
9	Import	Prevymis injection(letermovir)	MSD Korea Ltd	2018-12-26	[629] Miscellaneous Chemotherapeutics	prophylaxis of cytomegalovirus (CMV) infection and disease in adult CMV seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT)
10	Import	Prevymis tablet 480mg(letermovir)				
11	Import	Prevymis tablet 240mg(letermovir)				

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

2.2. Information on Approval of orphan drugs

As a chemical drug approved in 2018, the number of orphan drugs were 14 items (6 manufacture items and 8 imported items) and 3 items from them were orphan new drugs (Refer to Table 27).

According to drug classification code, they are 5 items of respiratory organ agents, 3 items of antineoplastic agents and 3 items of miscellaneous chemotherapeutics.

Table 27. Approval Status of Orphan Drug in 2018 (Chemical Drugs)

No.	Manufactured/ imported	Product name	Company	Approval Date	Code	Efficacy/Effects
1	Import	Acarizax 12SQ House Dust Mite sublingual tablet	Abbot Korea	2018-01-02	[149] Miscellaneous Allergic agents	treatment of moderate to severe house dust mite allergic rhinitis not well controlled despite use of symptom relieving medication in adults and ≥ 12 years treatment of house dust mite allergic asthma not well controlled despite use of symptom relieving medication in adults
2	Mfg.	Pir-M tablet 200mg(pirfenidone)	Mcnulty pharmaceutical Co., Ltd.	2018-03-14	[229] Miscellaneous Respiratory organ agents	treatment of idiopathic pulmonary fibrosis
3	Mfg.	Trientab capsule(trientine HCl)	Kolmar Korea Co., Ltd	2018-07-16	[392] Antidotes	treatment of patients with Wilson's disease who are intolerant of penicillamine
4	Mfg.	Fybro tablet 400mg(pirfenidone)	Yungjin Pharmaceutical Co., Ltd.	2018-07-30	[229] Miscellaneous Respiratory organ agents	treatment of idiopathic pulmonary fibrosis
5	Mfg.	Fybro tablet 600mg(pirfenidone)				
6	Import	Kuvalla soluble tablet 100mg (sapropterin dihydrochloride)	Samoh pharm. Co., Ltd	2018-07-31	[399] Miscellaneous metabolism agents	treatment of hyperphenylalaninemia(HPA) in adults and pediatric patients
7	Mfg.	Piresko tablet 400mg(pirfenidone)	Kolon Pharma	2018-10-15	[229] Miscellaneous Respiratory organ agents	treatment of idiopathic pulmonary fibrosis
8	Mfg.	Piresko tablet 600mg(pirfenidone)				
9	Import	Alunbrig tablet 30mg(brigatinib)	Takeda Korea Pharmaceutical	2018-11-30	[421] Antineoplastic agents	treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-
10	Import	Alunbrig tablet 90mg(brigatinib)				

11	Import	Alunbrig tablet 180mg(brigatinib)				small cell lung cancer (NSCLC) who have progressed on or are intolerant to crizotinib. Efficacy is based on response rate and duration of response, there is no evidence of improved survival.
12	Import (New drug)	Prevymis tablet 240mg(letermovir)	MSD Korea Ltd	2018-12-26	[629] Miscellaneous Chemotherapeutics	prophylaxis of cytomegalovirus (CMV) infection and disease in adult CMV seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT)
13	Import (New drug)	Prevymis tablet 480mg(letermovir)				
14	Import (New drug)	Prevymis injection(letermovir)				

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

2.3. Information on Approval of incrementally modified drugs

The number of incrementally modified drugs approved in 2018 is 6 items in total which were new formulation developed as SR tables from IR tablets. In 2016 and 2017, a development of new combinations of active ingredients was noticeable; the items developed as two-drug combination product hypertension or diabetes were approved as incrementally modified drugs in 2016 while items developed as three-drug combination product with different modes of action for hypertension were approved as incrementally modified drugs in 2017 (Refer to Table 28 and Table 29).

Table 28. Type of Incrementally Modified Drugs in 2014~2018

Year	New composition	New dosage form (Same route of administration)	New routes of administration	Total
2014	1	0	0	1
2015	7	11	0	18
2016	22	1	1	24

2017	7	4	0	11
2018	0	6	0	6

Table 29. List of Incrementally Modified Drugs (2009~2018)

No.	Product name	Company name	Approval Date	Drug Classification Code	Remarks
1	Amosartan Tablet 5/50 mg	Hanmi Pharmaceutical	2009-03-31	[214] Antihypertensives	Change of active substance type or compounding ratio
2	Amosartan Tablet 5/100 mg				
3	Cozaar XQ Tablet 5/50mg(amlodipine camsylate/losartan potassium)	MSD Korea LTD.	2009-11-20		
4	Cozaar XQ Tablet 5/100mg(amlodipine camsylate/losartan potassium)				
5	Potastine OD Tablet (Bepotastine calcium dihydrate)	Hanmi Pharmaceutical	2010-02-11	[141] Antihistamine	Sodium and formulation changes
6	CLANZA CR Tablet	Korea United Pharm Inc.	2010-04-14	[114] Antipyretics and analgesics, anti-inflammatory agents	Change in dosage form, strength and administration/dosage
7	Ridrone Plus Tablet	Pacific Pharmaceuticals	2010-06-23	[399] Miscellaneous metabolism agents	Change of active substance type or compounding ratio
8	RISENEX-PLUS Tablet	HANLIM PHARM.	2010-06-23		
9	Risenplus Tablet	DAEWOONG PHARMACEUTICAL	2010-06-23		
10	Amosartan Tablet 10/50 mg	Hanmi Pharmaceutical	2010-10-15	[214] Antihypertensives	Change of active substance type or compounding ratio
11	Cozaar XQ Tablet 10/50mg(amlodipine camsylate/losartan potassium)	MSD Korea LTD.	2010-10-15		
12	Ultracet ER Tablet	Janssen Korea	2010-11-22	[114] Antipyretics and	Change in dosage form, strength and administration/dosage

				analgesics, anti-inflammatory agents	
13	LOXFEN CR Tablet	SHINPOONG Pharmaceutical Co.	2011-03-18	[114] Antipyretics and analgesics, anti-inflammatory agents	Change in dosage form, strength and administration/dosage
14	Pletaal SR Capsules	Korea Otsuka Pharmaceutical	2011-04-19	[339] Other blood and body fluids	Change in dosage form, strength and administration/dosage
15	Apetrol ES Oral suspension	LG Life Science	2012-03-27	[421] Antineoplastic agents	Change in dosage form, strength and administration/dosage
16	Ridonel D Tablet	Hanmi Pharmaceutical	2012-04-03	[399] Miscellaneous metabolism agents	Change in dosage form, strength and administration/dosage
17	RISENEX-M Tablet	HANLIM PHARM.	2012-04-03		
18	Letopra Tablet 20mg	Ahngook Pharm.	2012-06-18	[232] Peptic ulcer agent	New sodium or isomers (first in Korea)
19	NASAFLEX Nasal Spray	HANLIM PHARM.	2012-11-16	[132] Otic and nasal agents	Change of substance type or compounding ratio
20	Moteson Plus Nasal Spray	Hanmi Pharmaceutical	2012-11-16		
21	KanarbPlus Tablets 120/12.5mg	Boryung Pharmaceutical	2013-01-04	[214] Antihypertensives	Change of substance type or compounding ratio
22	KanarbPlus Tablets 60/12.5mg				
23	OLMETAN Tablet 22.08mg (Olmesartan cilexetil)	JIN YANG PHARM. CO.	2013-01-31	[214] Antihypertensives	New sodium or isomers (first in Korea)
24	Olmexin S Tablet (Olmesartan medoxomil)	SK Chemicals			
25	Olmos-F Tablet 22.08mg (Olmesartan Cilexet il)	Ahngook Pharm.			

26	Olmexetil Tablet 22.08mg (Olmesartan Cilexetil)	JEIL PHARMACEUTICAL CO.,LTD.			
27	CILOSTAN CR 200 mg Tablet (Cilostazol)	Korea United Pharm Inc.	2013-02-28	[339] Miscellaneous blood and body fluids agents	Change in dosage form, strength and administration/dosage
28	Julian Tablet 15mg (Clomipramine hydrochloride)	Dongkook Pharm.	2013-03-20	[259] Miscellaneous Urogenital and anal organ agents	Apparently add another efficacy
29	Nenoma Tablet 15mg (Clomipramine HCl)	HUONS CO. LTD			
30	Condencia Tablet 15mg (clomipramine hydrochloride)	CTCBIO Inc.			
31	CLOJACK Tablet 15mg (Clomipramine hydrochloride)	JIN YANG PHARM. CO.			
32	VOGMET Tablet 0.2/250mg	CJ Healthcare	2013-06-17	[396] Antidiabetic agent	Change of substance type or compounding ratio
33	VOGMET Tablet 0.2/500mg				
34	Bonviva Plus Tablet	DreamPharma	2013-07-08	[399] Miscellaneous metabolism agents	Change of active substance type or compounding ratio
35	Levacalm Tablet 20/160mg	LG Chem.	2013-07-25	[214] Antihypertensives	Change of active substance type or compounding ratio
36	Levacalm Tablet 20/160mg				
37	Levacalm Tablet 10/80mg				
38	Zemimet SR Tablet 25/500mg	LG Chem.	2013-07-25	[396] Antidiabetic agent	Change of active substance type or compounding ratio
39	DEXID Tablet 480mg (R-thioctic acid tromethamine)	Bukwang Pharm.	2013-11-21	[399] Miscellaneous metabolism agents	New sodium or isomers (first in Korea)
40	Zemimet SR Tablet 50/1000mg	LG Chem.	2014-11-07	[396] Antidiabetic agent	Change of active substance type or compounding ratio

41	Sapodifil SR Tablet 300mg (Sarpogrelate HCl)	Alvogen Korea Co. Ltd	2015-01-23	[339] Miscellaneous blood and body fluids agents	Change in dosage form, strength and administration/dosage
42	Anpran SR Tablet 300mg (Sapogrelate Hydrochloride)	JEIL PHARMACEUTICAL CO.,LTD.			
43	Anpla X-SR Tablet 300mg (Sarpogrelate HCl)	SK Chemicals			
44	ANPLONE SR Tablet 300mg (Sarpogrelate hydrochloride)	DAEWOONG PHARMACEUTICAL			
45	ANFRADE SR Tablet 300mg (Sarpogrelate HCl)	CJ Healthcare			
46	PELUBI CR TABLET(Pelubiprofen)	Daewon Pharmaceutical	2015-03-13	[114] Antipyretics and analgesics, anti-inflammatory agents	Change in dosage form, strength and administration/dosage
47	Tenelia M SR tablet 10/750mg	Handok Inc.	2015-03-31	[396] Antidiabetic agent	Change of active substance type or compounding ratio
48	Tenelia M SR tablet 20/1000mg				
49	Tenelia M SR tablet 10/500mg				
50	EXON SR TABLET(eperisone hydrochloride)	AJU PHARMA CO.	2015-03-31	[122] Skeletal muscle relaxant	Change in dosage form, strength and administration/dosage
51	Exonin CR Tablet(Eperisone hydrochloride)	SK Chemicals			
52	EPESIN SR Tablet (eperisone hydrochloride)	Myungmoon Pharm.			
53	NEREXON SR TABLET(Eperisone hydrochloride)	Daewon Pharmaceutical			
54	Eperinal SR Tablet (Eperisone Hydrochloride)	JEIL PHARMACEUTICAL CO.,LTD.			
55	Zemimet SR Tablet50/500mg	LG Life Science	2015-10-12	[396] Antidiabetic agent	Change of active substance type or compounding ratio
56	Sugamet XR Tablet 2.5/500mg		2015-12-31	[396]	Change of active substance type

57	Sugamet XR Tablet 2.5/850mg	DONG-A ST		Antidiabetic agent	or compounding ratio
58	Sugamet XR Tablet 5/1000mg				
59	Dukarb Tablets 30/5mg	Boryung Pharmaceutical	2016-05-30	[214] Antihypertensives	Change of active substance type or compounding ratio
60	Dukarb Tablets 30/10mg				
61	Dukarb Tablets 60/5mg				
62	Dukarb Tablets 60/10mg				
63	KARBPIN Tablet 60/5 mg	Boryung Biopharma Co.	2016-05-31	[214] Antihypertensives	Change of active substance type or compounding ratio
64	KARBPIN Tablet 60/10 mg				
65	KARBPIN Tablet 30/5 mg				
66	KARBPIN Tablet 30/10 mg				
67	CANDEAMLO Tablet 16/10mg	SHINPOONG Pharmaceutical Co.	2016-06-24	[214] Antihypertensives	Change of active substance type or compounding ratio
68	CANDEAMLO Tablet 16/5mg				
69	CANDEAMLO Tablet 8/5mg				
70	MACHKHAN Tablet 8/5mg	CJ Healthcare	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 Tablet 0.25/750mg	Chong Kun Dang Pharm.	2016-06-30	[396] Antidiabetic agent	Change of active substance type or compounding ratio
74	Duvimet XR Tablet 0.25/1000mg				
75	Duvimet XR Tablet 0.5/1000mg				
76	GASTIIN CR Tablet(Mosapride citrate hydrate)	Korea United Pharm Inc.	2016-06-30	[239] Miscellaneous digestive organ agents	Change in dosage form, strength and administration/dosage
77	Zemimet SR Tablet 25/1000mg	LG Chem.	2016-06-30	[396] Antidiabetic agent	Change of active substance type or compounding ratio
78	Duvimet XR Tablet 0.25/500mg	Chong Kun Dang Pharm.	2016-09-01	[396] Antidiabetic agent	Change of active substance type or compounding ratio
79	LIPORAXEL Solution. (Paclitaxel)	Dae Hwa Pharmaceutical	2016-09-09	[421] Antineoplastic agents	New routes of administration

80	Safrep solution	CTCBIO INC.	2016-10-06	[721] X-ray contrast media	Change of active substance type or compounding ratio
81	Duocolon Solution 300mL	Alvogen Korea Co. Ltd	2016-10-06	[721] X-ray contrast media	Change of active substance type or compounding ratio
82	Coolipa Solution	Ahngook Pharm.	2016-10-06	[721] X-ray contrast media	Change of active substance type or compounding ratio
83	Surfolase CR Tablet (Acebrophylline)	Hyundai Pharm	2017-02-24	[229] Miscellaneous respiratory organ agents	Change in dosage form, strength and administration/dosage
84	LEVOTICS CR Tablet (Levodropropizine)	Korea United Pharm Inc.	2017-04-12	[222] Antitussive expectorants	Change in dosage form, strength and administration/dosage
85	Levocare CR Tablet (Levodropropizine)	KWANGDONG PHARMACEUTICAL	2017-04-12	[222] Antitussive expectorants	Change in dosage form, strength and administration/dosage
86	NEOTUSS CR Tablet (Levodropropizine)	JW Shinyak	2017-04-12	[222] Antitussive expectorants	Change in dosage form, strength and administration/dosage
87	Amosartan Plus Tablet 5/80/12.5 mg	Hanmi Pharmaceutical	2017-06-29	[214] Antihypertensives	Change of active substance type or compounding ratio
88	Amosartan Plus Tablet 5/100/12.5 mg				
89	Amosartan Plus Tablet 5/100/25 mg				
90	TWOTOPSPLUS TABLET 40/5/12.5mg	ILDONG PHARMACEUTICAL CO.	2017-07-25	[214] Antihypertensives	Change of active substance type or compounding ratio
91	TWOTOPSPLUS TABLET 80/5/12.5mg				
92	TWOTOPSPLUS TABLET 80/10/12.5mg				
93	TWOTOPSPLUS TABLET 80/10/25mg				
94	Belion SR tablet(bepostatine salicylate)	Hanlim Pharma. Co., Ltd	2018-07-30	[141] Antihistamine	change in dosage form, strength and administration/dosage
95	Tari-S SR tablet(bepostatine salicylate)	Sam Chun Dang Pharrm. Co., Ltd			
96	Beposta SR tablet(bepostatine salicylate)	Daewon Pharmaceutical Co., Ltd.			
97	Bepo-Q tablet(bepostatine salicylate)	Kwang Dong			

		Pharmaceutical Co., Ltd			
98	Bepotan SR tablet(bepostatine salicylate)	Dongkook Pharmaceutical Co., Ltd			
99	Beporine SR tablet(bepostatine salicylate)	Sama Pharm. Co., Ltd			

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

2.4. Information on Approval of Drugs Requiring Data Submission

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

Among the drugs requiring data submission (excluding incrementally modified drugs) approved in 2018, development of drugs with new composition or changes in content took the largest items (54.5%, 127 items), followed by drugs with new salts (30.3%, 70 items), drugs with new dosage form (same route of administration) (12.9%, 30 items) (Refer to Table 30).

Table 30. Approval Status of Drugs Requiring Data Submission in 2018

Review type of drugs requiring for data submission		No. of Approved Items	
New salts or isomers		70	
New composition or active ingredient or change only in contents	93	New composition	111
		Change in strength	16
New routes of administration		3	
New administration/ dosage		3	
New dosage form (same route of administration)		30	
Total		233	

* Excluding Incrementally Modified Drugs (Drugs requiring data submission)

1) Drugs with New salt or isomer (70 items)

The 70 chemical drug items approved as new salt or isomer (all manufactured items) are those either changed the salt from varenicline tartrate, aid to smoking cessation treatment into salicyliate, oxalic acid, besylate, fumarate [90% (63 items)]; or developed the dabigatran etexilate mesylate, anticoagulants, into Dabigatran etexilate [10% (7 items)] (Refer to Table 31).

Table 31. Approval Status of Drugs with New Salt or New Isomer that Require Data Submission in 2018

No.	Mfg./ Import	Product	Company	Approval Date	Code	Efficacy/Effectiveness	Remarks
1	Mfg.	Mc Clean tablet 0.5mg (varenicline salicylate)	Mcnulty pharmaceutical Co., Ltd.	2018-06-15	[799] Non-main therapeutic purpose agents	aid to smoking cessation treatment	tartrate → salicylate
2	Mfg.	Mc Clean tablet 1mg (varenicline salicylate)					
3	Mfg.	Chamclean tablet 0.5mg (varenicline salicylate)	Chong Kun Dang Pharm.	2018-06-15	[799] Non-main therapeutic purpose agents	aid to smoking cessation treatment	tartrate → salicylate
4	Mfg.	Chamclean tablet 1mg (varenicline salicylate)					
5	Mfg.	Yuyu Varenicline Salicylate tablet 0.5mg	Yuyu Pharma Inc.	2018-06-15	[799] Non-main therapeutic purpose agents	aid to smoking cessation treatment	tartrate → salicylate
6	Mfg.	Yuyu Varenicline Salicylate tablet 1mg					
7	Mfg.	Zerofix tablet 0.5mg (varenicline salicylate)	Jeil Pharmaceutical Co., Ltd	2018-06-15	[799] Non-main therapeutic purpose agents	aid to smoking cessation treatment	tartrate → salicylate
8	Mfg.	Zerofix tablet 1mg (varenicline salicylate)					
9	Mfg.	Nicoban tablet 0.5mg (varenicline salicylate)	Unimed Pharm Inc.	2018-06-15	[799] Non-main therapeutic purpose agents	aid to smoking cessation treatment	tartrate → salicylate
10	Mfg.	Nicoban tablet 1mg (varenicline salicylate)					
11	Mfg.	Nicobye tablet 0.5mg (varenicline salicylate)	Samjin Pharm Co., Ltd	2018-06-15	[799] Non-main	aid to smoking cessation	tartrate → salicylate

12	Mfg.	Nicobye tablet 1mg (varenicline salicylate)			therapeutic purpose agents	treatment	
13	Mfg.	Nicofence tablet 0.5mg (varenicline salicylate)	C-TRI Co., Ltd	2018-06-15	[799] Non-main therapeutic purpose agents	aid to smoking cessation treatment	tartrate → salicylate
14	Mfg.	Nicofence tablet 1mg (varenicline salicylate)					
15	Mfg.	champion tablet 0.5mg (varenicline salicylate)	Korea Prime Pharm Co., Ltd	2018-06-15	[799] Non-main therapeutic purpose agents	aid to smoking cessation treatment	tartrate → salicylate
16	Mfg.	champion tablet 1mg (varenicline salicylate)					
17	Mfg.	Chamstop tablet 0.5mg (varenicline salicylate)	Hana Pharm Co., Ltd	2018-06-15	[799] Non-main therapeutic purpose agents	aid to smoking cessation treatment	tartrate → salicylate
18	Mfg.	Chamstop tablet 1mg (varenicline salicylate)					
19	Mfg.	Cleanfix tablet 0.5mg (varenicline salicylate)	Pharvis Korea	2018-06-15	[799] Non-main therapeutic purpose agents	aid to smoking cessation treatment	tartrate → salicylate
20	Mfg.	Cleanfix tablet 1mg (varenicline salicylate)					
21	Mfg.	Yeonhu tablet 0.5mg (varenicline salicylate)	Boryung Co., Ltd	2018-06-15	[799] Non-main therapeutic purpose agents	aid to smoking cessation treatment	tartrate → salicylate
22	Mfg.	Yeonhu tablet 1mg (varenicline salicylate)					
23	Mfg.	Chamtops tablet 0.5mg (varenicline salicylate)	IlDong Pharmaceutical Co., Ltd	2018-06-15	[799] Non-main therapeutic purpose agents	aid to smoking cessation treatment	tartrate → salicylate
24	Mfg.	Chamtops tablet 1mg (varenicline salicylate)					
25	Mfg.	Nico-X tablet 0.5mg (varenicline salicylate)	Daehan New Pharm Co., Ltd	2018-06-18	[799] Non-main therapeutic purpose agents	aid to smoking cessation treatment	tartrate → salicylate
26	Mfg.	Nico-X tablet 1mg (varenicline salicylate)					
27	Mfg.	Nicopix tablet 0.5mg	Hutecs Korea	2018-07-	[799] Non-	aid to smoking	tartrate →

		(varenicline salicylate)	Pharmaceutical Co., Ltd	12	main therapeutic purpose agents	cessation treatment	salicylate
28	Mfg.	Nicopix tablet 1mg (varenicline salicylate)					
29	Mfg.	Nocotine tablet 0.5mg (varenicline oxalate hydrate)	Hanmi Pharmaceutical Co., Ltd	2018-08-08	[799] Non-main therapeutic purpose agents	aid to smoking cessation treatment	tartrate → oxalate hydrate
30	Mfg.	Nocotine tablet 1mg (varenicline oxalate hydrate)					
31	Mfg.	Smofix tablet 0.5mg (varenicline salicylate)	Kwang Dong Pharmaceutical Co., Ltd	2018-08-14	[799] Non-main therapeutic purpose agents	aid to smoking cessation treatment	tartrate → salicylate
32	Mfg.	Smofix tablet 1mg (varenicline salicylate)					
33	Mfg.	Chamkis taablet 0.5mg (varenicline salicylate)	Daewoong Pharamaceutical Co., Ltd	2018-08-14	[799] Non-main therapeutic purpose agents	aid to smoking cessation treatment	tartrate → salicylate
34	Mfg.	Chamkis taablet 1mg (varenicline salicylate)					
35	Mfg.	Zerocotine tablet 0.5mg (varenicline salicylate)	Inist Bio Pharmaceutical Co., Ltd	2018-08-14	[799] Non-main therapeutic purpose agents	aid to smoking cessation treatment	tartrate → salicylate
36	Mfg.	Zerocotine tablet 1mg (varenicline salicylate)					
37	Mfg.	Stobacco tablet 0.5mg (varenicline salicylate)	Korea United Pharm Inc.	2018-08-14	[799] Non-main therapeutic purpose agents	aid to smoking cessation treatment	tartrate → salicylate
38	Mfg.	Stobacco tablet 1mg (varenicline salicylate)					
39	Mfg.	Tabatect tablet 0.5mg (varenicline salicylate)	Korean Drug Co., Ltd	2018-08-14	[799] Non-main therapeutic purpose agents	aid to smoking cessation treatment	tartrate → salicylate
40	Mfg.	Tabatect tablet 1mg (varenicline salicylate)					
41	Mfg.	Nicost tablet 0.5mg (varenicline salicylate)	JW shinyak	2018-08-14	[799] Non-main therapeutic purpose	aid to smoking cessation treatment	tartrate → salicylate
42	Mfg.	Nicost tablet 1mg (varenicline salicylate)					

					agents		
43	Mfg.	Nicobreak tablet 0.5mg (varenicline salicylate)	CTC Bio Co., Ltd	2018-08-14	[799] Non-main therapeutic purpose agents	aid to smoking cessation treatment	tartrate → salicylate
44	Mfg.	Nicobreak tablet 1mg (varenicline salicylate)					
45	Mfg.	Varecl tablet 0.5mg (varenicline salicylate)	KyoungBo Pharmaceutical Co., Ltd	2018-08-14	[799] Non-main therapeutic purpose agents	aid to smoking cessation treatment	tartrate → salicylate
46	Mfg.	Varecl tablet 1mg (varenicline salicylate)					
47	Mfg.	Topfix tablet 0.5mg (varenicline salicylate)	Alvogen Korea Co., Ltd	2018-08-16	[799] Non-main therapeutic purpose agents	aid to smoking cessation treatment	tartrate → salicylate
48	Mfg.	Topfix tablet 1mg (varenicline salicylate)					
49	Mfg.	Cryfix tablet 0.5mg (varenicline salicylate)	Crystal Life Science	2018-08-16	[799] Non-main therapeutic purpose agents	aid to smoking cessation treatment	tartrate → salicylate
50	Mfg.	Cryfix tablet 1mg (varenicline salicylate)					
51	Mfg.	Geumfix tablet 0.5mg (varenicline salicylate)	Daewoong Bio Co., Ltd	2018-08-16	[799] Non-main therapeutic purpose agents	aid to smoking cessation treatment	tartrate → salicylate
52	Mfg.	Geumfix tablet 1mg (varenicline salicylate)					
53	Mfg.	Nicover tablet 0.5mg (varenicline salicylate)	Whanin pharm. Co.,Ltd	2018-08-17	[799] Non-main therapeutic purpose agents	aid to smoking cessation treatment	tartrate → salicylate
54	Mfg.	Nicover tablet 1mg (varenicline salicylate)					
55	Mfg.	Renico tablet 0.5mg (varenicline besylate monohydrate)	KyungDong Pharm. Co., Ltd.	2018-10-10	[799] Non-main therapeutic purpose agents	aid to smoking cessation treatment	tartrate → besylate monohydrate
56	Mfg.	Renico tablet 1mg (varenicline besylate monohydrate)					
57	Mfg.	Jtran capsule 110mg	Jeil	2018-11-	[333]	1. Reduction of	dabigatran

		(dabigatran etexilate)	Pharmaceutical Co., Ltd	15	Anticoagulants	risk of stroke and systemic embolism in non-valvular atrial fibrillation	etexilate mesylate → dabigatran etexilate
58	Mfg.	Jtran capsule 150mg (dabigatran etexilate)					
59	Mfg.	Myungin Dabigatran capsule 110mg (dabigatran etexilate)	Myung In Pharm. Co. Ltd	2018-11-15	[333] Anticoagulants	1. Reduction of risk of stroke and systemic embolism in non-valvular atrial fibrillation	dabigatran etexilate mesylate → dabigatran etexilate
60	Mfg.	Myungin Dabigatran capsule 150mg (dabigatran etexilate)					
61	Mfg.	Dabiran capsule 110mg (dabigatran etexilate)	Samjin Pharm Co., Ltd	2018-11-15	[333] Anticoagulants	1. Reduction of risk of stroke and systemic embolism in non-valvular atrial fibrillation	dabigatran etexilate mesylate → dabigatran etexilate
62	Mfg.	Dabiran capsule 150mg (dabigatran etexilate)					
63	Mfg.	Dabidaxa capsule 110mg (dabigatran etexilate)	Daewon Pharmaceutical Co., Ltd.	2018-11-15	[333] Anticoagulants	1. Reduction of risk of stroke and systemic embolism in non-valvular atrial fibrillation	dabigatran etexilate mesylate → dabigatran etexilate
64	Mfg.	Dabidaxa capsule 150mg (dabigatran etexilate)					
65	Mfg.	Yooradaxa capsule 110mg (dabigatran etexilate)	YooYoungG Co., Ltd	2018-11-15	[333] Anticoagulants	1. Reduction of risk of stroke and systemic embolism in non-valvular atrial fibrillation	dabigatran etexilate mesylate → dabigatran etexilate
66	Mfg.	Yooradaxa capsule 150mg (dabigatran etexilate)					
67	Mfg.	Dabiall capsule 110mg (dabigatran etexilate)	Dasan pharmaceutical Co., Ltd	2018-11-15	[333] Anticoagulants	1. Reduction of risk of stroke and systemic embolism in non-valvular atrial fibrillation	dabigatran etexilate mesylate → dabigatran etexilate
68	Mfg.	Dabiall capsule 150mg (dabigatran etexilate)					

69	Mfg.	varenistop tablet 0.5mg (varenicline fumarate)	Kolmar Korea	2018-12-17	[799] Non-main therapeutic purpose agents	aid to smoking cessation treatment	tartrate → fumarate
70	Mfg.	varenistop tablet 1mg (varenicline fumarate)					

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

2) Drugs with new composition or changes in strength of active substances (127 items)

In case of drugs with new composition, 111 items (101 manufactured items and 10 imported items) were approved. Out of them, cardiovascular agents were 56 items (50.4%) and metabolism agents (antidiabetic agents and miscellaneous metabolism agents) were 51 items (45.9%). Among them, antihypertensive/antihyperlipidemic combination products with rosuvastatin calcium as an active ingredient were 47 items, accounted for 42.3% of the new composition drugs approved in 2018. 27 antidiabetic/antihyperlipidemic combination drugs composed of Metformin HCl and statin (atorvastatin or rosuvastatin) (24.3%) were approved (Refer to Table 32).

In case of drugs with new changes in contents (11 manufactured items and 6 imported items), 16 items were approved there was no specific item with drug classification code taking the most of them (Refer to Table 33).

Table 32. Approval Status of Drugs with New Composition that Require Data Submission in 2018

No.	Mfg/ import	Product	Supplier	Approval date	Code	Active ingredient
1	Mfg.	Novacan tablet 16/5mg	Hanall Biopharma Co., Ltd	2018-01-08	[214] Antihypertensives	candesartan cilexetil, amlodipine besylate
2	Mfg.	Daviroad tablet 16/5mg	Green Cross Corp.	2018-01-08	[214] Antihypertensives	candesartan cilexetil, amlodipine besylate
3	Mfg.	Canstar-X tablet 16/5mg	DongKawang Pharmaceutical Co., Ltd	2018-01-08	[214] Antihypertensives	candesartan cilexetil, amlodipine besylate
4	Import	Skudexa tablet	Menarini Korea Limited	2018-04-04	[114] Antipyretics and analgesics, anti-inflammatory agents	dexketoprofen trometamol, tramadol hydrochloride

5	Mfg.	Monterizine chewable tablet	Hanmi Pharmaceutical Co., Ltd	2018-04-16	[149] Micscellaneous Allergic agnets	montelukast sodium, levocetirizine hydrochloride
6	Mfg.	Eso Duo tablet 20/800mg	Chong Kun Dang Pharmaceutical Corp.	2018-04-30	[232] peptic ulcer agents	esomeprazole magnesium trihydrate, sodium bicarbonate
7	Mfg.	Lipito-M SR tablet 10/500mg	Jeil Pharmaceutical Co., Ltd	2018-05-10	[396] Antidiabetic agents	metformin hydrochloride, atorvastatin calcium hydrate
8	Mfg.	Lipito-M SR tablet 10/750mg				
9	Mfg.	Lipito-M SR tablet 20/500mg				
10	Mfg.	Lipito-M SR tablet 20/750mg				
11	Mfg.	Telmiduo Plus tablet 80/5/10mg	Jeil Pharmaceutical Co., Ltd	2018-05-10	[219] Miscellaneous Cardiovascular agents	telmisartan, amlodipine besylate, rosuvastatin calcium
12	Mfg.	Telmiduo Plus tablet 80/10/20mg				
13	Mfg.	Telmiduo Plus tablet 40/5/10mg				
14	Mfg.	Lipimet SR tablet 10/500mg	Daewoong Pharamaceutical Co., Ltd	2018-05-10	[396] Antidiabetic agents	metformin hydrochloride, atrovastatin calcium hydrate
15	Mfg.	Lipimet SR tablet 10/750mg				
16	Mfg.	Lipimet SR tablet 20/500mg				
17	Mfg.	Lipimet SR tablet 20/750mg				
18	Mfg.	Telostop Plus tablet 40/5/10mg	IlDong Pharmaceutical Co., Ltd	2018-05-10	[219] Miscellaneous Cardiovascular agents	telmisartan, amlodipine besylate, rosuvastatin calcium
19	Mfg.	Telostop Plus tablet 80/10/20mg				
20	Mfg.	Telostop Plus tablet 80/5/10mg				
21	Mfg.	Telostop Plus tablet 80/5/5mg				
22	Mfg.	Telostop Plus tablet 80/10/10mg				
23	Mfg.	Telostop Plus tablet 40/5/5mg				
24	Mfg.	Atomet SR tablet 10/500mg	CJ Healthcare Corp.	2018-05-10	[396] Antidiabetic agents	metformin hydrochloride, atrovastatin calcium

25	Mfg.	Atomet SR tablet 10/750mg				hydrate
26	Mfg.	Atomet SR tablet 20/750mg				
27	Mfg.	Atomet SR tablet 20/500mg				
28	Import	Trelegy Ellipta	GlaxoSmithKline korea	2018-05-11	[229] Miscellaneous Respiratory organ agents	flutocasone furoate(micronized), umeclidinium bromide(micronized), vilanterol trifenatate(micronized)
29	Mfg.	Neustatin-TS tablet 80/5/10mg	Samjin Pharm Co., Ltd	2018-05-30	[219] Miscellaneous Cardiovascular agents	telmisartan, amlodipine besylate, rosuvastatin calcium
30	Mfg.	Neustatin-TS tablet 40/5/10mg				
31	Mfg.	Neustatin-TS tablet 80/10/20mg				
32	Mfg.	Tri-in-one tablet 80/10/20mg	Daewon Pharmaceutical Co., Ltd.	2018-05-30	[219] Miscellaneous Cardiovascular agents	telmisartan, amlodipine besylate, rosuvastatin calcium
33	Mfg.	Tri-in-one tablet 80/10/10mg				
34	Mfg.	Tri-in-one tablet 80/5/10mg				
35	Mfg.	Tri-in-one tablet 80/5/5mg				
36	Mfg.	Tri-in-one tablet 40/5/10mg				
37	Mfg.	Tri-in-one tablet 40/5/5mg				
38	Mfg.	Treble tablet 80/10/10mg	Celltrion Pharm, Inc	2018-06-20	[219] Miscellaneous Cardiovascular agents	telmisartan, amlodipine besylate, rosuvastatin calcium
39	Mfg.	Treble tablet 80/5/5mg				
40	Mfg.	Treble tablet 40/5/5mg				
41	Mfg.	Treble tablet 80/5/10mg				
42	Mfg.	Treble tablet 40/5/10mg				
43	Mfg.	Treble tablet 80/10/20mg				
44	Mfg.	Triflow tablet 80/5/10mg	Ilyang	2018-05-30	[219]	telmisartan, amlodipine

45	Mfg.	Triflow tablet 40/5/10mg	Pharmacuetical Co., Ltd		Miscellaneous Cardiovascular agents	besylate, rosuvastatin calcium
46	Mfg.	Triflow tablet 80/10/20mg				
47	Mfg.	Telminuvo-S tablet 80/10/20mg	Chong Kun Dang Pharmaceutical Corp.	2018-05-30	[219] Miscellaneous Cardiovascular agents	telmisartan, amlodipine besylate, rosuvastatin calcium
48	Mfg.	Telminuvo-S tablet 80/5/10mg				
49	Mfg.	Telminuvo-S tablet 40/5/10mg				
50	Mfg.	Rosumet SR tablet 10/500mg	Yuhan Corp.	2018-06-20	[396] Antidiabetic agents	metformin hydrochloride, rosuvastatin calcium
51	Mfg.	Rosumet SR tablet 5/500mg				
52	Mfg.	Rosumet SR tablet 5/750mg				
53	Mfg.	Rosumet SR tablet 10/750mg				
54	Mfg.	Rosumet SR tablet 20/500mg				
55	Mfg.	Rosumet SR tablet 20/750mg				
56	Import	Edarbyclor 40/25mg	Takeda Pharmaceuticals korea	2018-08-06	[214] Antihypertensives	azilsartan medoxomil potassion, chlortalidone
57	Import	Edarbyclor 40/12.5mg				
58	Mfg.	Lipito-M SR tablet 10/1000mg	Jeil Pharmaceutical Co., Ltd	2018-08-14	[396] Antidiabetic agents	metformin hydrochloride, atorvastatin calcium hydrate
59	Mfg.	Lipimet SR tablet 10/1000mg	Daewoong Pharamaceutical Co., Ltd	2018-08-14	[396] Antidiabetic agents	metformin hydrochloride, atorvastatin calcium hydrate
60	Mfg.	Atomet SR tablet 10/1000mg	CJ Healthcare Corp.	2018-08-16	[396] Antidiabetic agents	metformin hydrochloride, atorvastatin calcium hydrate
61	Mfg.	Togenon tablet 5/16mg	Dong-A ST	2018-08-28	[219] Miscellaneous Cardiovascular agents	rosuvastatin calcium, candesartan cilexetil
62	Mfg.	Bazestar tablet	Yuyu Pharma Inc.	2018-08-28	[399] Miscellaneous metabolism agents	bazedoxifene acetate, cholecalciferol concentrate powder

63	Mfg.	ViboneD tablet	Yungjin Pharmaceutical Co., Ltd.	2018-08-28	[399] Miscellaneous metabolism agents	bazedoxifene acetate, cholecalciferol concentrate powder
64	Mfg.	Rocanduo tablet 5/16mg	Alvogen Korea Co., Ltd	2018-08-28	[219] Miscellaneous Cardiovascular agents	rosuvastatin calcium, candesartan cilexetil
65	Mfg.	Bonemore-D tablet	Alvogen Korea Co., Ltd	2018-08-28	[399] Miscellaneous metabolism agents	bazedoxifene acetate, cholecalciferol concentrate powder
66	Mfg.	Combirocan tablet	Whanin pharm. Co.,Ltd	2018-08-28	[219] Miscellaneous Cardiovascular agents	rosuvastatin calcium, candesartan cilexetil
67	Mfg.	Bafene-D tablet	Hanwha Pharma Co., Ltd	2018-08-28	[399] Miscellaneous metabolism agents	bazedoxifene acetate, cholecalciferol concentrate powder
68	Mfg.	Bachol D tablet	Daewha pharmaceutical	2018-08-28	[399] Miscellaneous metabolism agents	bazedoxifene acetate, cholecalciferol concentrate powder
69	Mfg.	Bonabone tablet	KyungDong Pharm. Co., Ltd.	2018-08-28	[399] Miscellaneous metabolism agents	bazedoxifene acetate, cholecalciferol concentrate powder
70	Mfg.	Badoxi Puls tablet	Hana Pharm Co., Ltd	2018-08-28	[399] Miscellaneous metabolism agents	bazedoxifene acetate, cholecalciferol concentrate powder
71	Mfg.	Rotacand tablet 5/16mg	Green Cross Corp.	2018-08-28	[219] Miscellaneous Cardiovascular agents	rosuvastatin calcium, candesartan cilexetil
72	Mfg.	Bodybone tablet	Hanlim Pharma. Co., Ltd	2018-08-28	[399] Miscellaneous metabolism agents	bazedoxifene acetate, cholecalciferol concentrate powder
73	Mfg.	Baze Plus tablet	IlDong Pharmaceutical Co., Ltd	2018-08-28	[399] Miscellaneous metabolism agents	bazedoxifene acetate, cholecalciferol concentrate powder
74	Mfg.	Vivian-D tablet	Bukwang pharm. Co., Ltd	2018-08-28	[399] Miscellaneous metabolism agents	bazedoxifene acetate, cholecalciferol concentrate powder
75	Mfg.	Rosuampin tablet 5/5mg	Yuhan Corp.	2018-08-31	[219] Miscellaneous Cardiovascular	rosubastatin calcium, amlodipine besylate
76	Mfg.	Rosuampin tablet 20/5mg				

77	Mfg.	Rosuampin tablet 10/5mg			agents	
78	Mfg.	Rosuampin tablet 20/10mg				
79	Mfg.	Anante tablet	Aju Pharm Co., Ltd	2018-09-03	[399] Miscellaneous metabolism agents	bazedoxifene acetate, cholecalciferol concentrate powder
80	Import	Stegluzan tablet 5/100mg	MSD korea Ltd	2018-09-05	[396] Antidiabetic agents	ertugliflozin L-pyroglutamic acid, sitagliptin phosphate
81	Import	Stegluzan tablet 1/100mg				
82	Mfg.	Bazefene Puls tablet	Dongkook Pharmaceutical Co., Ltd	2018-09-10	[399] Miscellaneous metabolism agents	bazedoxifene acetate, cholecalciferol concentrate powder
83	Mfg.	Telmidipine R 40/5/10mg	Hana Pharm Co., Ltd	2018-09-18	[219] Miscellaneous Cardiovascular agents	telmisartan, amlodipine besylate, rosuvastatin calcium
84	Mfg.	Telmidipine R 80/5/10mg				
85	Mfg.	Vivant Puls D tablet	Huons Co., Ltd	2018-09-28	[399] Miscellaneous metabolism agents	bazedoxifene acetate, cholecalciferol concentrate powder
86	Mfg.	Telmiroad Q tablet 80/5/10mg	Ahngook pharmaceutical Co., Ltd	2018-10-02	[219] Miscellaneous Cardiovascular agents	telmisartan, amlodipine besylate, rosuvastatin calcium
87	Mfg.	Telmiroad Q tablet 80/5/5mg				
88	Mfg.	Telmiroad Q tablet 40/5/10mg				
89	Mfg.	Telmiroad Q tablet 40/5/5mg				
90	Mfg.	Rosutanmet tablet 500/10mg	Dongkook Pharmaceutical Co., Ltd	2018-10-10	[396] Antidiabetic agents	metformin hydrochloride, rosuvastatin calcium
91	Mfg.	Rosutanmet tablet 750/10mg				
92	Mfg.	Crevis tablet 500/10mg	Kukje Pharmaceutical Co., Ltd	2018-10-10	[396] Antidiabetic agents	metformin hydrochloride, rosuvastatin calcium
93	Mfg.	Crevis tablet 750/10mg				
94	Mfg.	Duomet XR tablet 750/10mg	Jeil Pharmaceutical Co., Ltd	2018-10-10	[396] Antidiabetic agents	metformin hydrochloride, rosuvastatin calcium
95	Mfg.	Duomet XR tablet 500/10mg				
96	Mfg.	Bazecal D tablet	Shinpoong Pharm. Co, Ltd	2018-10-10	[399] Miscellaneous metabolism agents	bazedoxifene acetate, cholecalciferol concentrate powder

97	Import	Seviact HCT tablet 10/40/12.5mg	Synex consulting Ltd	2018-10-10	[214] Antihypertensives	olmesartan medoxomil, amlodipine besylate, hydrochlorothiazide
98	Import	Seviact HCT tablet 5/40/12.5mg				
99	Import	Seviact HCT tablet 5/20/12.5mg				
100	Mfg.	Uniant D tablet	Union Korea Pharm. Co., Ltd	2018-10-11	[399] Miscellaneous metabolism agents	bazedoxifene acetate, cholecalciferol concentrate powder
101	Mfg.	Bazerol tablet	Therazen Etex Co., Ltd	2018-10-11	[399] Miscellaneous metabolism agents	bazedoxifene acetate, cholecalciferol concentrate powder
102	Mfg.	Babibon tablet	Hyundai Pharm. Co., Ltd	2018-10-11	[399] Miscellaneous metabolism agents	bazedoxifene acetate, cholecalciferol concentrate powder
103	Mfg.	Hubant Plus D tablet	Humedix Co., Ltd	2018-10-18	[399] Miscellaneous metabolism agents	bazedoxifene acetate, cholecalciferol concentrate powder
104	Mfg.	AID-bone B tablet	Samjin Pharm Co., Ltd	2018-10-18	[399] Miscellaneous metabolism agents	bazedoxifene acetate, cholecalciferol concentrate powder
105	Mfg.	Bazetamin D tablet	Boryung Co., Ltd	2018-10-18	[399] Miscellaneous metabolism agents	bazedoxifene acetate, cholecalciferol concentrate powder
106	Import	Nesina Met tablet 12.5/850mg	Takeda Pharmaceuticals korea	2018-10-31	[396] Antidiabetic agents	alogliptin benzoate, metformin hydrochloride
107	Mfg.	Duowell A tablet 80/5/5mg	Yuhan Corp.	2018-11-27	[219] Miscellaneous Cardiovascular agents	telmisartan, amlodipine besylate, rosuvastatin calcium
108	Mfg.	Duowell A tablet 80/5/20mg				
109	Mfg.	Duowell A tablet 40/5/5mg				
110	Mfg.	Venusplus tablet	Hutex Korea Pharmaceutical Co., Ltd	2018-12-26	[399] Miscellaneous metabolism agents	bazedoxifene acetate, cholecalciferol concentrate powder
111	Mfg.	Duowell A tablet 40/5/20mg	Yuhan Corp.	2018-12-26	[219] Miscellaneous Cardiovascular agents	telmisartan, amlodipine besylate, rosuvastatin calcium

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

Table 33. Approval Status of Drugs with Changes in strength of active substances that Require Data Submission in 2018

No.	Manufactured/ imported	Product name	Company name	Approval Date	Drug classification code	Efficacy/Effectiveness
1	Mfg.	Clavixin Duo capsule 75/75mg	Korea United Pharm Inc.	2018-02-08	[218] Hyperlipidemia agents	Clavixin Duo Capsule can be used in adult patients only with following disease who should administer clopidogrel and aspirin simultaneously
2	Import	Epiduoforte gel 0.3%/2.5% (adapalene/benzoyl peroxide)	Galderma Korea	2018-02-27	[266] Emollients	treatment of moderate and severe acne vulgaris, characterized by comodones, inflammatory papules/pustules in patients 12 years of age and older
3	Mfg.	Scoterin Plus solution (peracetic acid solution)	Huons Medicare Co., Ltd	2018-02-28	[739] Miscellaneous public health agents	sterilization and disinfection of medical device
4	Mfg.	Scosingle solution (peracetic acid solution)	Huons Medicare Co., Ltd	2018-04-16	[739] Miscellaneous public health agents	sterilization and disinfection of medical device
5	Mfg.	Azalid Injection 150mg (azacitidine)	Samyang Biopharmaceuticals corp.	2018-05-31	[421] Antineoplastic agents	1. Myelodyplastic syndrome(MDS)
6	Import	Isentress HD tablet (raltegravir potassium (milcronized))	MSD korea Ltd	2018-06-29	[629] Miscellaneous Chemotherapeutics	Adult patients: combination with other antiretroviral agents for the treatment HIV-1 infection in adult patients
7	Mfg.	Decilid Injection 40mg (decitabine)	Samyang Biopharmaceuticals corp.	2018-07-25	[421] Antineoplastic agents	1. treatment of patients with Myelodyplastic syndrome(MDS)

8	Mfg.	Anarid capsule 1mg (anagrelide hydrochloride)	Pharmbio Korea Inc.	2018-08-31	[429] Miscellaneous antitumors	following symptom improvement of patients with thrombocytosis due to myeloproliferative disorder(essential thrombocythemia, polycythemia vera, chronic myeloid leukemia, other myeloproliferative disorder)
9	Import	Azilect tablet 0.5mg (rasagiline mesylate)	Lundbeck Korea Co., Ltd	2018-09-03	[119] Miscellaneous central nervous system	treatment of idiopathic Parkinson's disease
10	Mfg.	Anagre capsule 1mg (anagrelide hydrochloride)	Yuhan Corp.	2018-09-12	[429] Miscellaneous antitumors	following symptom improvement of patients with thrombocytosis due to myeloproliferative disorder(essential thrombocythemia, polycythemia vera, chronic myeloid leukemia, other myeloproliferative disorder)
11	Mfg.	Emtimol solution (citruline malate)	Mcnulty pharmaceutical Co., Ltd.	2018-09-27	[399] Miscellaneous metabolism agents	symptomatic treatment of functional asthenia
12	Mfg.	Zanapam tablet 0.125mg (alprazolam)	Myung In Pharm. Co. Ltd	2018-10-04	[117] Psychotropics	1. treatment of anxiety disorder and short-term relieve of anxiety symptoms
13	Mfg.	Clzapine tablet 50mg (clozapine)	Dong Wha Pharma Co., Ltd	2018-10-24	[117] Psychotropics	1. treatment-resistant schizophrenia or treatment of schizophrenia patients who have severe extrapyramidal adverse reaction(in particular, tardive dystkinesia) to other antipsychotic agents
14	Mfg.	Clzapine tablet 200mg (clozapine)	Dong Wha Pharma Co., Ltd	2018-11-12		
15	Import	Bicored tablet 22400 IU	BL&H Co., Ltd	2018-11-16	[311] Vitamin A and D preparations	Prevention of Vitamin D deficiency

		(cholecalciferol concentrated powder)				
16	Import	Zeljanz tablet 10mg (tofacitinib citrate)	Pfizer Korea Ltid	2018-12-03	[142] Non-specific Immunosuppressants	1. Ulcerative Colitis

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

3) Drugs with new administration route (3 items)

Chemical drugs approved with new administration route were 3 imported items including the following: a hormone agent previously approved for dermal use now developed to be nasal use; other chemical agent previously approved for oral or external use developed into an agent for application to mouth; and a hormone agent previously approved as muscle injection developed into hypodermic injection (Refer to Table 34).

Table 34. Approval Status of Drugs with New Route of Administration Requiring Data Submission in 2018

No.	Product	Company	Approval Date	Code	Efficacy/Effectiveness (partially summarized)	New route of administration
1	Natesto Nasal Gel(testosterone)	Hyundai Pharm. Co., Ltd	2018-06-05	[246] Androgen preparations	Testosterone replacement therapy for male hypogonadism	Dermal → Nasal
2	Sitavig Muco-Adhesive buccal tablet(aciclovir)	Daewoong Pharamaceutical Co., Ltd	2018-08-02	[629] Miscellaneous Chemotherapeutics	treatment of recurrent herpes labiatis in immunocompetent adult patient	oral, external → oro-mucosal
3	Prolutex Injection 25mg (progesterone)	Eisen Pharma Korea	2018-12-31	[247] Estrogen and progesterone preparation	luteal phase support in an assisted reproductive technique(ART) programme who are unable to use of tolerate vaginal preparations	IM inj. → SC inj.

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

4) Drugs with New dosage/ administration (3 items)

The chemical drugs approved with a new administration and dosage are 3 imported items which are percutaneous absorbing agents used for pain relief (Refer to Table 35).

Table 35. Approval Status of Drugs with New Dosage/Administration that Require Data Submission in 2018

No.	Mfg/ Import	Product	Company	Approval Date	Code	Efficacy/Effects
1	Import	Buprein patch 35μg/h(buprenorphine)	Myungmoon Pharm. Co., Ltd	2018-05-08	[264] Analgesics, anti-itchings, astringents, anti-inflammatory agents	Relief of moderate to severe cancer pain which does not respond to non-opioid analgesics. This drug is not suitable for the treatment of acute pain.
2	Import	Buprein patch 50μg/h(buprenorphine)				
3	Import	Buprein patch 70μg/h(buprenorphine)				

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

5) Drugs with new dosage form (same route of administration) (30 items)

Chemical drugs approved with new administration routes were 30 items (4 imported items and 26 manufactured items). According to development type, 16 items (53.3%) were developed from capsule into tablet; 5 items from liquid or ointment into absorbent (drugs included in cotton swab, gauze, etc.); 4 items from IR tables (tablet or capsule) into SR tablets; and 2 items from tablet into other oral solid drugs (ODF and granule) (See Table 36).

Table 36. Approval Status of Drugs with New Dosage Form (Same Route of Administration) that Require Data Submission in 2018

No.	Mfg/ Import	Product	Company	Approval Date	Code	Efficacy/Effectiveness (Partially summarized)	New dosage
1	Mfg.	Gumi Hexi-isopropyl Stick Solution	Gumi Pharm Corp.	2018-01-22	[261] Antimicrobial agents	- disinfection of the skin surgical procedures - disinfection of the patient's skin prior to syringe needle or catheter insertion	liquid → adsorbent

2	Mfg.	Meinta Injection 100mg (pemetrexed disodium 2.5 hydrate)	Dong-A ST	2018-01-31	[421] Antineoplastic agents	combination with cisplatin is indicated for the treatment of chemotherapy naive patients with unsectable malignant pleural mesothelioma	freeze dried powder inj. → liquid inj.
3	Mfg.	Unigrel CR Tablet (sarpogrelate hydrochlroride)	Korea United Pharm Inc.	2018-02-23	[339] Miscellaneous Blood and body fluid agents	Improvement of ischemic symptoms such asulceration, pain and cold feeling caused by chronic arterial occlusion (Burger's disease, occlusive atherosclerosis, diabetic peripheral vascular disease, etc.)	IR tablet → SR tablet
4	Import	BD Chloraprep Swabstick	Becton-Dickinson Korea	2018-03-22	[261] Antimicrobial agents	disinfection of the skin surgical procedures, disinfection of the patient's skin prior to syringe needle or catheter insertion	liquid → adsorbent
5	Mfg.	Q&Q Hexidine Stick Swap Solution	Q&Q Pharm.	2018-03-28	[261] Antimicrobial agents	- disinfection of hands and skin - disinfection of the skin surgical area	liquid → adsorbent
6	Mfg.	Q&Q Nitrofurazone Gauze	Q&Q Pharm.	2018-06-18	[263] Suppurative dermatosis agents	Secondary bacterial infection by burn or superficial wound	ointment → adsorbent
7	Mfg.	Tamin B ODF	Seoul Pharma Co., Ltd	2018-06-21	[313] Vitaimin B preperation	relieve of following symptoms: angular stomatitis, cheilitis, stomatitis, glossitis, eczema and dermatitis	tablet → ODF
8	Mfg.	Jdart tablet 0.5mg (dutasteride)	JW Pharmaceutical Corp.	2018-06-29	[259] Miscellaneous Urogenital and anal organ agents	treatment of benign prostatic hyperplasia	capsule → tablet

9	Mfg.	Dutavan Plus tablet (dutasteride)	Dong-A ST	2018-07-04	[259] Miscellaneous Urogenital and anal organ agents	treatment of benign prostatic hyperplasia	capsule → tablet
10	Mfg.	NP-dart tablet (dutasteride)	Daehan New Pharm Co., Ltd	2018-07-04	[259] Miscellaneous Urogenital and anal organ agents	treatment of benign prostatic hyperplasia	capsule → tablet
11	Mfg.	Neodart tablet 0.5mg (dutasteride)	JW Shinyak	2018-07-04	[259] Miscellaneous Urogenital and anal organ agents	treatment of benign prostatic hyperplasia	capsule → tablet
12	Mfg.	Duamo tablet (dutasteride)	Kwang Dong Pharmaceutical Co., Ltd	2018-07-06	[259] Miscellaneous Urogenital and anal organ agents	treatment of benign prostatic hyperplasia	capsule → tablet
13	Mfg.	Duro Care tablet 0.5mg(dutasteride)	Hana Pharm Co., Ltd	2018-07-06	[259] Miscellaneous Urogenital and anal organ agents	treatment of benign prostatic hyperplasia	capsule → tablet
14	Mfg.	Dutacare tablet 0.5mg (dutasteride)	Dasan pharmaceutical Co., Ltd	2018-07-06	[259] Miscellaneous Urogenital and anal organ agents	treatment of benign prostatic hyperplasia	capsule → tablet
15	Mfg.	Dutes tablet 0.5mg (dutasteride)	Nexpharm Korea	2018-07-09	[259] Miscellaneous Urogenital and anal organ agents	treatment of benign prostatic hyperplasia	capsule → tablet
16	Mfg.	Avogro tablet 0.5mg (dutasteride)	Korea Global Pharm	2018-07-09	[259] Miscellaneous Urogenital and anal organ agents	treatment of benign prostatic hyperplasia	capsule → tablet

17	Mfg.	Onetwosteride tablet 0.5mg(dutasteride)	Hutecs Korea Pharmaceutical Co., Ltde	2018-07-10	[259] Miscellaneous Urogenital and anal organ agents	treatment of benign prostatic hyperplasia	capsule → tablet
18	Mfg.	Dutaron tablet 0.5mg(dutasteride)	Alvogen Korea Co., Ltd	2018-07-10	[259] Miscellaneous Urogenital and anal organ agents	treatment of benign prostatic hyperplasia	capsule → tablet
19	Mfg.	Daewoong Bio Dutasteride tablet 0.5mg	Daewoong Bio Co., Ltd	2018-07-10	[259] Miscellaneous Urogenital and anal organ agents	treatment of benign prostatic hyperplasia	capsule → tablet
20	Mfg.	Choliacenrid Capsule (Choline alfoscerate)	Kolma Pharma	2018-07-12	[119] Miscellaneous central nervous system	degenerative or involutive cerebral psycho-organic syndromes or secondary to cerebrovascular insufficiency	soft capsule →hard capsule
21	Mfg.	Dutav tablet 0.5mg (dutasteride)	APROGEN Pharm.	2018-07-13	[259] Miscellaneous Urogenital and anal organ agents	treatment of benign prostatic hyperplasia	capsule → tablet
22	Mfg.	Dutalid tablet 0.5mg (dutasteride)	Dongu Bio Pharm.	2018-07-13	[259] Miscellaneous Urogenital and anal organ agents	treatment of benign prostatic hyperplasia	capsule → tablet
23	Mfg.	Damodat tablet 0.5mg (dutasteride)	Seoul Pharma Co., Ltd	2018-07-13	[259] Miscellaneous Urogenital and anal organ agents	treatment of benign prostatic hyperplasia	capsule → tablet
24	Import	Lyrica CR tablet 330mg (pregabalin)	Pfizer Korea Ltid	2018-07-18	[119] Miscellaneous central nervous system	treatment of peripheral neuropathic pain in adults	capsule → SR
25	Import	Lyrica CR tablet 165mg (pregabalin)					

26	Import	Lyrica CR tablet 82.5mg (pregabalin)					
27	Mfg.	OB Care ODF 10mg	Seoul Pharma Co., Ltd	2018-07-19	[259] Miscellaneous Urogenital and anal organ agents	treatment of irritable bladder syndrome such as overactive bladder, urinary frequency and urinary urgency	tablet → ODF
28	Mfg.	Avotars tablet (dutasteride)	Korea Pharm	2018-07-30	[259] Miscellaneous Urogenital and anal organ agents	treatment of benign prostatic hyperplasia	capsule → tablet
29	Mfg.	Solt Stick Solution	Green Pharm.	2018-08-10	[261] Antimicrobial agents	sterilization and disinfection of scratches, cuts and wound surface	liquid → adsorbent
30	Mfg.	Withfull Granule	Intropharm	2018-10-31	[399] Miscellaneous metabolism agents	supportive therapy of weight loss (reduction) through reduction of food intake	tablet → granule

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

3. Information on Approval of Biopharmaceuticals

3. Information on Approval of Biopharmaceuticals

According to the analysis of biopharmaceuticals approved in 2018 based on regulatory review pathways, there were 4 new drugs, 31 drugs requiring data submission (23 other drugs requiring data submission) and 1 orphan drugs (excluding 1 orphan new drugs) (Refer to Table 37), More specifically, 11 biologics, 22 recombinant protein products, and 3 other products (human placenta-derived drugs) were approved (Refer to Table 38).

Table 37. Approvals Status of Biopharmaceuticals by Review Type in 2018

<Including Drugs for Export Only and Drug Substances>

No.	Review Type	No. of Approved Products		
		Total	Manufactured	Imported
1	New drugs	4	0	4
1-1	New drugs	3	0	3
1-2	Orphan new drugs	1	0	1
2	Orphan drugs (except for Orphan new drugs)	1	0	1
3	Drugs requiring data submission	31	23	8
3-1	Incrementally modified drugs	0	0	0
3-2	Biosimilar products	8	7	1
3-3	Other drugs requiring data submission	23	16	7
3-4	Cell therapy Products	0	0	0
Total		36	23	13

***** Including 3 human placenta-derived drugs out of 23 other drugs requiring data submission

<Excluding Drugs for Export Only and Drug Substances >

No.	Review Type	No. of Approved Products		
		Total	Manufactured	Imported
1	New drugs	4	0	4
1-1	New drugs	3	0	3
1-2	Orphan new drugs	1	0	1
2	Orphan drugs (except for Orphan new drugs)	1	0	1
3	Drugs requiring data submission	23	15	8
3-1	Incrementally modified drugs	0	0	0
3-2	Biosimilar products	8	7	1
3-3	Other drugs requiring data submission	15	8	7
3-4	Cell therapy Products	0	0	0
Total		28	15	13

* Including 3 human placenta-derived drugs out of 15 other drugs requiring data submission

Table 38. Approval Status of Biopharmaceuticals in 2018
< Including Drugs for Export Only and Drug Substances >

Types	Total	No. of Approved Items		Remarks
		Manufactured	Imported	
Total	**36**	**23**	**13**	
Biologics	11	8	3	Drugs requiring data submission (11, including 4 drugs for export only)
Recombinant Protein products	22	12	10	New drugs (4), orphan (1, excluding orphan new drugs), drugs requiring data submission (17, including Drugs for Export Only(2) and Drug Substances(2))
Cell therapy products	0	0	0	-
Gene therapy products	0	0	0	-
Others	3	3	0	Human placenta-derived drug (3)

3.1. Information on Approval of Biologics

In 2018, 11 biologics were approved (8 manufactured products, 3 imported product/ 9 vaccines, 1 botulinum toxin, and 1 blood product), 12 items (11 manufactured products, 1 imported product/ 8 vaccines, 2 botulinum toxins, and 2 blood products) in 2017, 20 items (15 manufactured products, 5 imported product/ 16 vaccines and 4 botulinum toxins) in 2016 were approved. The approval in 2018 decreased from 2016, but similar to 2017.

Vaccines approved in 2018 include 6 influenza vaccines, 1 typhoid vaccine, 1 varicella vaccine and 1 combined vaccine (Refer to Table 39).

For influenza vaccine, the World Health Organization (WHO) recommends developing quadrivalent vaccines containing 4 types of viruses (A (H1N1, H3N2), B (both "Yamagata" and "Victoria") in order to avoid mismatch between the B type virus contained in the influenza vaccine and the most dominant flu strain. All 4 items approved for domestic use in 2018 are Influenza prevention vaccines, FluPlus Tetra Prefilled Syringe Inj. of LG Chemicals and BR Flutech I Tetra Vaccine Inj. (PFS) of Boryung Pharmaceutical were approved. Teratect Prefilled Syringe Inj., Il-yang Flu Vaccine Prefilled Inj., Teratect Final Bulk and Il-yang Flu Vaccine Final Bulk are the items of Il-yang Pharm. As a result, the seasonal influenza vaccines became a total of 63 items in 2018 with 4 additional approved finished products.

'Vivotif Oral Capsule.' is a product which Daewoong Pharm. succeeded its status through transfer of the approved import item from Terabox Korea. This product is a vaccine for the prevention of typhoid fever in children aged more than 5 years or older and adults.

'SkyVaricella Inj. of SK Chemicals is a varicella vaccine developed with domestic technologies and is a product that succeeded in localization and self-sufficiency through customized consulting of the "Global Vaccine Product Support Group" operated by MFDS. This product is a vaccine administered for prevention of chickenpox in children between 12 months and 12 years old.

'Infanrix-IPV Hip Inj.' of GlaxoSmithKline is a combined vaccine for prevention of invasive diseases caused by diphtheria, tetanus, pertussis, polio, and haemophilus influenza type b.

In case of the botulinum toxin products, 4 items were newly approved in 2016, 2 items in 2017, and 1 item in 2018 respectively (Refer to Table 39)., 'Xeomin Inj. 50Unit' of MERZ Pharmaceutical Asia Pacific Pte Ltd. is a product which was developed into other units from the previously approved product with the same effectiveness and efficacy.

In case of blood products, there was no product approved in 2016 but 2 items in 2017 and 1 item of the plasma fraction preparation were approved in 2018 (Refer to Table 39).

'Tetabulin SN Prefilled Syringe Inj. (anti-tetanus human immunoglobulin) of SK Plasma is a product developed into another container from the approved product with the same effectiveness and efficacy

MFDS has operated Global Vaccine Commercialization Support Group from 2010 as part of the customized support to enhance Korea's capacity for vaccine self-sufficiency which has greatly contributed to the development and subsequent approvals of a cholera vaccine, quadrivalent influenza vaccines and a pre-pandemic influenza vaccine in 2015, followed by continued development and approvals of a combined diphtheria and tetanus vaccine for adults in 2016 and a shingles vaccine in 2017. MFDS will continue to provide technical support to increase the nation's self-sufficiency of essential preventive vaccines and core vaccines.

Table 39. List of Approved Biologics in 2018

No.	Mfg./ Imported	Product name	Ingredients	Company	Approval Date	Efficacy/Effectiveness	Remarks
1	Mfg.	Fluplus Tetra Prefilled Syringe Inj	Purified influenza virus antigen(Split virion, Inactivated) A(H1N1), A(H3N2), B(Yamagata), B(Victoria)	LG Chem, Ltd.	2018-03-29	Prophylaxis against influenza caused by influenza A subtype viruses and type B viruses in persons aged 6 months and older	Requiring data submission

2	Import	Xeomin Inj. 50 Unit (Clostridium Botulinum A Type(150kDa))	Botulinum toxin type A (150 kDa)	Merz Pharmaceutical Asia Pacific Pte Ltd.	2018-04-05	Indicated for the temporary improvement in the appearance of upper facial lines in adults 1. Transient Improvement in moderate or severe glabellar frown lines related with the activity of corrugator muscle and/or procerus muscle in adults 18 years of age or more and 65 years of age or less. 2. Transient Improvement in moderate to severe lateral periorbital lines (crow's feet lines) related with the activity of orbicular oculi muscle in adults 18 years of age or more and 65 years of age or less. 3. Transient Improvement in moderate to severe horizontal forehead lines related with the activity of venter frontalis muscle in adults 18 years of age or more and 65 years of age or less.	Requiring data submission
3	Import	Vivotif Oral capsules	Typhoid Vaccine Live Oral Ty21a	Daewoong Pharmaceutical Co., Ltd.	2018-04-09	immunization of adults and children greater than 5 years of age against disease caused by Salmonella typhi	Requiring data submission
4	Mfg	BR FLUTECT I TETRA Vaccine INJ. (Prefilled Syringes)	Purified influenza virus antigen(Split virion, Inactivated) A(H1N1), A(H3N2), B(Yamagata), B(Victoria)	Boryung Pharmaceutical Co., Ltd	2018-05-11	Prophylaxis against influenza caused by influenza A subtype viruses and type B viruses in persons aged 6 months and older	Requiring data submission
5	Mfg	SKYVaricella Inj.	Live, attenuated varicella-zoster virus	SK bioscience Co., Ltd.	2018-06-04	Prophylaxis against varicella in persons aged 12 months ~ 12 years old	Requiring data submission
6	Mfg	Tetabulin SN Inj. Prefilled Syringe	Human Tetanus Immunoglobulin	SK Plasma Co., Ltd.	2018-10-25	Prophylaxis and treatment of tetanus	Requiring data submission

7	Import	INFANRIX-IPV Hib injection	Diphtheria toxoid, Tetanus toxoid, Pertussis toxoid, Filamentous haemagglutinin, 69 kDa Outer Membrane Protein, Inactivated Polio Virus Type 1, Inactivated Polio Virus Type 2, Inactivated Polio Virus Type 3, Haemophilus influenzae type b capsular polysaccharide conjugated to tetanus toxoid	GlaxoSmithKline	2018-10-26	Active immunisation against diphtheria, tetanus, pertussis, poliomyelitis and Haemophilus influenzae type b disease from the age of 2 months	Requiring data submission
8	Mfg	TERATECT Prefilled Syringe INJ(For Export)	Purified inactivated influenza virus antigen A(H1N1), A(H3N2), B(Yamagata), B(Victoria)	IL-YANG PHARM. CO., LTD.	2018-04-03	Prophylaxis against influenza caused by influenza A subtype viruses and type B viruses in persons aged 3 years and older	Requiring data submission (For export only)
9	Mfg	IL-YANG Flu Vaccine Prefilled Syringe INJ(For Export)	Purified inactivated influenza virus antigen A(H1N1), A(H3N2), B(Yamagata), B(Victoria)	IL-YANG PHARM. CO., LTD.	2018-04-06	Prophylaxis against influenza caused by influenza A subtype viruses and type B virus in persons aged 6 months and older	Requiring data submission (For export only)
10	Mfg	TERATECT Final Bulk(For Export)	Purified inactivated influenza virus antigen A(H1N1), A(H3N2), B(Yamagata), B(Victoria)	IL-YANG PHARM. CO., LTD.	2018-04-03	Manufacture of finished products	Requiring data submission (Final Bulk, For export only)
11	Mfg	IL-YANG FLU Vaccine Final Bulk(For Export)	Purified inactivated influenza virus antigen A(H1N1), A(H3N2), B(Yamagata), B(Victoria)	IL-YANG PHARM. CO., LTD.	2018-04-06	Manufacture of finished products	Requiring data submission (Final Bulk, For export only)

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

3.2. Information on Approval of Recombinant Protein Products

22 recombinant protein products were approved in 2018 (12 manufactured items and 10 imported items) including 4 new drugs (including orphan new drugs), 1 orphan drug (excluding 1 orphan new drug) and 17 drugs requiring data submission (2 items for export and 2 items of drug substance) (Refer to Table 40).

In 2018, items designated as new drugs (including orphan drugs) were a total of 4 ingredients and 4 items. New drugs approved (or converted) in 2017 were 7 ingredients and 13 items, 4 new drug items were approved in 2018, so new drug approval decreased YoY. In addition, 1 item of orphan drugs (excluding orphan new drug) was approved, decreased from 2 items YOY.

'Dupixent Prefilled Inj. 300 mg (DUPILUMAB) ' (SANOFI-AVENTIS KOREA, Mar 30, 2018) was approved as a new drug which combines with alfa subunit (IL-4Rα/IL- 13Rα) of type 1 and type 2 interleukin-4/13 receptor specifically, inhibits IL-4 and IL-13 signaling and used in treatment of atopic dermatitis.

'Tremfya Prefilled Syringe Inj. (Guselkumab)' (Janssen Korea, Apr 12, 2018) is IgG1λ monoclonal antibody neutralizes the biological activity by binding into p19 subtype of interleukin-23 and was approved as a new drug used in treatment of moderate to severe adult psoriasis requiring phototherapy or systemic therapy

'Gattex Inj. (Teduglutide)' (Shire Pharma Korea, Aug 17, 2018) is a genetic recombinant analog of human glucagon-like peptide which binds to the GLP-2 receptor such as enteroendocrine cell and an orphan new drug which was developed for treatment of adult and child patients with short bowel syndrome (SBS) who depend on parenteral nutrition.

'Imfinzi Inj. (Durvalumab)' (AstraZeneca Korea, Dec 4, 2018) is an immune anti-cancer drug which blocks the reciprocal interaction between programmed cell death Ligand-1(PD-L1) and programmed cell death-1(PD-1) or CD80 selectively by binding to PD-L1, and approved as new drug used in treatment of patients with non-locally advanced and not severable non-small cell lung cancer whose diseases are not in progress after platinum-based concurrent chemoradiation radiation therapy

'ILARIS solution for injection (Canakinumab)' (Novartis Korea, Aug 9, 2018) is a product which was developed as a new formulation (liquid vial) with the same administration route with the previously approved ILARIS Inj.(freeze dry vial) and was approved as an orphan drug with the same effectiveness and efficacy with ILARIS Inj.

For biosimilar products, 3 type of ingredients and 8 items were approved. Since the approval of monoclonal antibody biosimilar drug item in 2012 for the first time in the world, a total of 13 types and 21 items were approved until 2018 and the domestically developed biosimilar drugs are a total of 9 types and 15 items (Refer to Table 41).

'Glarzia Prefilled Pen (Insulin glargine)' (Green Cross, Mar 7, 2018) is a biosimilar product which was developed compared against reference product, Lantus Injection (insulin glargine) of SANOFI-AVENTIS KOREA.

'Eucept Prefilled Syringe Inj. (Etanercept), Eucept AutoInjector Inj. (Etanercept) '(LG Chem., Mar 16, 2018) is a biosimilar product which was developed compared against reference product, Enbrel 25mgPrefilled Inj. (Etanercept) and Enbrel 50mgPrefilled Inj. (Etanercept).

Nesbell PFS Inj.20/30/40/60/120(darbepoetin alfa) (Nov 29, 2018) of Chong Kun Dang Pharmaceutical is a biosimilar product which was developed compared against reference product, Nesp Prefilled Syringe (darbepoetin alfa) of Kyowakirin Korea.

'Adynovate Inj. (Rurioctocog ala pegol)' (Shire Pharma Korea, Jan 31, 2018) is an item which improved the half-life of the existing blood coagulation agent VIII factor item, ADVATE INJ. through pegylation

'Stelara Intravenous Inj. (Ustekinumab)' (Janssen Korea, Apr 6, 2018) is a product developed to be administered intravenously for induction therapy in adult Crohn's disease and approved for use in maintenance therapy of Stelara Prefilled inj. or Stelara SC Inj. approved already to patients who responded to induction therapy.

'Fiasp Flex Touch Inj. 100 U/ mL (insulin aspart), Fiasp Inj. 100U/ mL (insulin aspart) ' (Novo Nordisk Pharmacy, Jul 13, 2018) is a gene recombinant drug that has been developed as a fast-acting insulin aspart with early insulin absorption and fast action time compared to NovoRapid Inj. the insulin product approved already.

In 2018, the number of general item approval cases including new drugs tends to be decreased compared with 2017, but the domestically developed biosimilar products were approved at the similar level to that of 2017.

40. List of Approved Recombinant Protein Products in 2018

No.	Mfg/ import	Product	Ingredient	Company	Date of approval	Efficacy/effectivenes (Partially summarized)	Remarks
1	Import	Dupixent Prefilled Inj. 300mg	Dupilumab	SANOFI-AVENTIS KOREA	2018-03-30	treatment of adult patients with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. DUPIXENT can be used with or without topical therapy.	New drug
2	Import	Tremfya Prefilled Syringe Inj.	Guselkumab	Janssen Korea	2018-04-12	Plaque psoriasis Indicated for treatment of adult patients with moderate to severe psoriasis who are candidates for phototherapy or systemic therapy.	New drug

3	Import	Gattex Inj.	Teduglutide	Shire Pharma Korea	2018-08-17	treatment of patients aged 1 year and above with Short Bowel Syndrome who are dependent on parenteral support	Orphan new drug
4	Import	Imfinzi Inj.	Durvalumab	Astra Zeneca Korea	2018-12-04	Treatment of patients with locally advanced, unresectable non-small cell lung cancer whose disease has not progressed following concurrent platinum-based chemoradiation therapy	New drug
5	Import	Ilaris Injection Sol.	Canakinumab	Novartis Korea	2018-08-09	1. Cryopyrin-related cyclic syndrome 2. Systemic pediatric idiopathic arthritis	Orphan
6	Import	Glarzia Prefilled Pen	Insulin glargine	Green Cross	2018-03-07	Diabetes requiring insulin therapy in children more than 2 year, adolescents and adults	Biosimilar
7	Mfg.	Eucept Prefilled Syringe Inj	Etanercept	LG Chem.	2018-03-16	1. Adults: Rheumatoidarthritis, psoriaticarthritis, congenital spondyloarthritis and psoriasis 2. Child: Childhood idiopathic arthritis	Biosimilar
8	Mfg.	Eucept Auto Injector Inj.					Biosimilar
9	Mfg.	Nesbell PFS Inj. 20	Darbepoetin alfa	Chong Kun Dang Pharmaceutical Corp	2018-11-29	1. Anemia in patients with chronic renal failure 2. Anemia by chemotherapy of solid cancer	Biosimilar
10	Mfg.	Nesbell PFS Inj.30					Biosimilar
11	Mfg.	Nesbell PFS Inj.40					Biosimilar
12	Mfg.	Nesbell PFS Inj.60					Biosimilar
13	Mfg.	Nesbell PFS Inj.120					Biosimilar
14	Import	Adynovate Inj	Rurioctocog Alfa Pegol(antihemophilic factor VIII)	Shire Pharma Korea	2018-01-31	Antihemophilic Factor (Recombinant), PEGylated, is a human antihemophilic factor indicated in children, adolescents, and adults with hemophilia A (congenital factor VIII deficiency) for: • On-demand treatment and control of bleeding episodes • Perioperative management	Requiring data submission

						• Routine prophylaxis to reduce the frequency of bleeding episodes	
15	Import	Stelara I.V. Inj.	Ustekinumab	Janssen Korea	2018-04-06	Crohn's Disease indicated for the treatment of moderately to severely active Crohn's disease in adults who have failed or were intolerant to or have medical contraindications to corticosteroids or immunomodulators, or anti-TNFα treatment.	Requiring data submission
16	Import	Fiasp 100 units/mL solution for injection in pre-filled pen	Insulin aspart	Novo Nordisk Phaermacy	2018-07-13	Treatment of diabetes mellitus in adults requiring insulin therapy	Requiring data submission
17	Import	Fiasp 100 units/mL solution for injection in vial					Requiring data submission
18	Mfg.	Eutropin Inj. 12IU	Somatropin	LG Chem.	2018-12-03	1. Paediatric Patients: Growth disturbance due to insufficient secretion of growth hormone and etc. 2: Adults Patients: Replacement therapy in adults with pronounced hormone deficiency as diagnosed in two dynamic tests for growth hormone deficiency	Requiring data submission
19	Mfg.	GreenGene F bulk solution	beroctocog alfa(antihemophilic factor VIII)	Green Cross	2018-17-19	Manufacture of finished products	Drug substance
20	Mfg.	Dong-A Recombinant human erythropoietin bulk solution II (Drug substance)	Recombinant human erythropoietin	Dong-A ST	2018-09-14	Pharmaceutical preparation and manufacturing	Drug substance

21	Mfg.	Erisa Prefilled Inj. 2000IU(for export)	Epoetin-alfa	PenGen Biotech Inc.	2018-04-04	erythropoiesis-stimulating agent indicated for ; 1) Treatment of symptomatic anaemia associated with chronic renal failure in adult and paediatric patients 2) Treatment of anaemia associated with chronic renal failure in adult and paediatric patients on haemodialysis 3) Treatment of adult patients in an autologous predonation program	For export only
22	Mfg.	Erisa Prefilled Inj. 4000IU(for export)					For export only

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

Table 41. List of Approved Biosimilars (2012~2018)

No.	Product name	Company	Reference Product (API)	Efficacy/effectiveness (Partially summarized)	Approval Date	Manufactured /Imported
1	Remsima Injection100mg	Celltrion	Remicade (Infliximap)	Rheumatoid arthritis, Ulcerative colitis, etc.	2012-07-20	Manufactured
2	Herzuma Injection150mg	Celltrion	Herceptin (Trastuzumab)	Breast cancer, Gastric cancer	2014-01-15	Manufactured
3	Herzuma Injection440mg	Celltrion	Herceptin (Trastuzumab)	Breast cancer, Gastric cancer	2014-01-15	Manufactured
4	Scitropin A cartridge Injection 5mg	Scigen Korea Ltd.	Genotropin (somatropin)	Poor growth of children	2014-01-.28	Imported
5	Scitropin A cartridge Injection 10mg	Scigen Korea Ltd	Genotropin (somatropin)	Poor growth of children	2014-01-.28	Imported
6	Davictrel Injection injection 25 mg	Hanwha Chemical	Enbrel (Etanercept)	Rheumatoid arthritis, Psoriasis	2014-11-11 (Withdrawal 2015-09-30)	Manufactured
7	Brenzys 50mg Prefilled Syringe→ (name change) Etoloce 50mg Prefilled Syringe	Samsung Bioepis	Enbrel (Etanercept)	Rheumatoid arthritis, Psoriasis	2015-09-07	Imported (Domestically developed)

8	Basaglar Cartridge 100Unit/mL	Lilly Korea Ltd.	Lantus (Insulin glargine)	Diabetes	2015-11-25	Imported
9	Basaglar Kwikpen 100Unit/mL	Lilly Korea Ltd.	Lantus (Insulin glargine)	Diabetes	2015-11-25	Imported
10	Renflexis Injection 100mg→ (name change) Remaloce Injection 100mg	Samsung Bioepis	Remicade (Infliximab)	Rheumatoid arthritis, Ulcerative colitis, etc.	2015-12-04	Imported (Domestically developed)
11	Truxima Injection	Celltrion	Mabthera (Rituximab)	Rheumatoid arthritis, Lymphoma, etc.	2015-07-16 (export only) 2016-11-16	Manufactured
12	Hadlima Prefilled Syringe Injection 40mg→ (name change) Adalloce Prefilled Syringe Injection 100mg	Samsung Bioepis	Humira (adalimumab)	Rheumatoid arthritis, Psoriatic arthritis etc.	2017-09-20	Imported (Domestically developed)
13	Samfenet Injection 150mg	Samsung Bioepis	Herceptin (Trastuzumab)	Breast cancer, Gastric cancer	2017-11-08	Imported (Domestically developed)
14	Glarzia Prefilled Pen	Green Cross	Lantus (Insulin glargine)	Diabetes	2018-03-07	Import
15	Eucept Prefilled Syringe Inj.	LG Chem.	Enbrel (Etanercept)	Rheumatoid arthritis, psoriasis, etc.	2018-03-16	Mfg.
16	Eucept Auto Injector Inj.	LG Chem.	Enbrel (Etanercept)	Rheumatoid arthritis, psoriasis, etc.	2018-03-16	Mfg.
17	Nesbell PFS Inj. 20	Chong Kun Dang Pharm.	Nesp (Darbepoetin alpha)	Anemia in patients with chronic renal failure, etc.	2018-11-29	Mfg.
18	Nesbell PFS Inj.30	Chong Kun Dang Pharm.	Nesp (Darbepoetin alpha)	Anemia in patients with chronic renal failure, etc	2018-11-29	Mfg.
19	Nesbell PFS Inj.40	Chong Kun Dang Pharm.	Nesp (Darbepoetin alpha)	Anemia in patients with chronic renal failure, etc	2018-11-29	Mfg.
20	Nesbell PFS Inj.60	Chong Kun Dang Pharm.	Nesp (Darbepoetin alpha)	Anemia in patients with chronic renal failure, etc	2018-11-29	Mfg.

21	Nesbell PFS Inj.120	Chong Kun Dang Pharm.	Nesp (Darbepoetin alpha)	Anemia in patients with chronic renal failure, etc	2018-11-29	Mfg.

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

3.3. Information on Approval of Cell Therapy Products

Since 'Chondron', domestically developed, was approved as the first cell therapy product in Korea in 2001, 15 products have been approved to date (Refer to Table 42).

After approval of ROSMIR in 2017, there was no cell therapy product approval in 2018. However, approval of the cell therapy product is expected to increase in the future through newly enacted conditional approval system (Jul, 2016 ~) for the cell therapy products for treatment of life-threatening disease or severe irreversible diseases.

Table 42. List of Approved Cell Therapy Products (2001~2018)

No.	Manufactured/ Imported	Product name	Ingredients	Company	Approval Date	Efficacy/effectiveness (Partially summarized)	Remarks
1	Manufactured	Chondron	Autologous chondrocytes	Sewon Cellontech	2001-01-30	Treatment of focal cartilage defect in knee joint (defect size: not more than 15cm^2 in single lesion, not more than 20cm^2 in multiple lesion)	
2	Manufactured	Holoderm	Autologous keratinocytes	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	
3	Manufactured	Kaloderm	Allogeneic keratinocytes	Tego Science, Inc.	2005-03-21 2010-06-24	1. Promoting re-epithelization of deep-seated second degree burn, 2. Promoting wound healing of diabetic foot ulcer	

4	Manufactured	Keraheal	Basol Autologous keratinocyte	Biosolution	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 Injection	Autologous dendritic cells	JW CreaGene	2007-05-15	Metastatic renal cell carcinoma capable of nephrectomy	
6	Manufactured	Immune cell LC Injection	Autologous Activated T Lymphocytes	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 Osteoblasts	Sewon Cellontech	2009-08-26	Promoting local bone formation	
8	Manufactured	Queencell	Minimally manipulated autologous-adipose cells	ANTEROGEN	2010-03-26	Improvement of subcutaneous fat defect	
9	Manufactured	CureSkin Injection	Autologous dermal fibroblasts	S Biomedics	2010-05-11	Improvement of dented scar area came from the acne treatment process	
10	Manufactured	Hearticellgram-AMI	Autologous bone marrow-derived mesenchymal stem cells	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	Human Umbilical Cord Blood-derived Mesenchymal Stem Cells	Medipost Co.	2012-01-18	Treatment of knee cartilage defects in patients with degenerative or repetitive traumatic osteoarthritis(ICRS grade IV)	
12	Manufactured	Cupistem	Autologous adipose-	ANTEROGEN	2012-01-18	Treatment of fistula due to Crohn's disease	Orphan drug

			derived mesenchymal stem cells				
13	Manufactured	Neuronata R Injection	Autologous bone marrow-derived mesenchymal stem cells	Corestem Inc.	2014-07-30	Alleviate the disease progression rate of amyotrophic lateral sclerosis in combination with riluzole	Orphan drug
14	Manufactured	Keraheal-Allo	Allogeneic keratinocytes	Biosolution	2015-10-16	Promoting re-epithelization of deep second degree burn	
15	Manufactured	Rosmir	Autologous fibroblasts	Tego Science, Inc.	2017-12-27	Improvement of moderate-to-severe nasojugal groove	

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

4. Information on Approval of Herbal Medicinal Products

4. Information on Approval of Herbal Medicinal Products

Herbal Medicinal Products approved in 2018 is a 42 items, increased by 83.3 %, 62.9 % and 41.9 % respectively, as compared with 24 items in 2014, 27 items in 2015, 31 items in 2016, but decreased by 5 % from 44 items in 2017 (Refer to Table 44).

According to an analysis by review type, there were 1 orphan drug, 2 drugs requiring data submission, 1 item formulated with a new administration route (external use), and 1 formulated with a new type (soft extract). In addition, there were 28 items approved by proving the equivalence included in bioequivalence test with new drugs, taking the most, 8 items approved for herbal health insurance medicine based on Herbal medicinal products based on Korean medicine book and 2 items of drug substance and 1 item of herbal substance.

Table 43. Approval Status of Herbal Medicinal Products by Review Type in 2018

(Unit: number of items)

Type	Review type		No. of Approved Items		
Total			Total	Manufactured	Imported
			42	41	1
1	New drugs		0	0	0
2	Orphan drugs		1	0	1
3-1	Drug requiring data submission	New composition and specification	0	0	0
3-2		Change in contents	0	0	0
3-3		New efficacy and effectiveness and dosage	0	0	0
		New routes of administration	1	1	0
		New formulation	1	1	0
3-4		When the documents are based on documents other than Korean Medicine book	0	0	0
4	Proof of equivalence		28	28	0
5	Other medicines	Herbal medicinal products based on Korean medicine book	8	8	0
		Drug Substance	2	2	0

		Herbal substance	1	1	0

When classified into 'Medical Product Classification Standards, 29 prescription drugs, 10 OTC drugs and 2 drug substances and 1 herbal substance were included (Refer to Table 45).

Table 44. Approval Status of Herbal Medicinal Products 2018

Types	Item	Total	Item Approval			
			Prescribed	OTC	Drug Substance	Herbal substances
Total		**42**	29	10	2	1
Herbal Medicinal Products	Manufactured	**41**	28	10	2	1
	Imported	**1**	1	0	0	0

4.1 Information on Approval of Herbal Medicinal products as Prescription Drug

From the herbal medicinal product approved in 2018, prescription drugs were 1 imported item and 28 domestically manufactured items manufactured with 3 ingredients (Refer to Table 46).

'Nexobrid Gel (pineapple hydrolase extract) 5g' is a drug that has already been designated as an orphan drug in many countries including Europe and is classified as a prescription drug/ orphan drug in Korea. Active ingredient was designated as orphan drug in 2015, recognizing its need to supply as a medicine for removal of crusta from adults due to deep second and third degree burns and notified in [Appendix 1] Pineapple hydrolase extract (gel) in accordance with the revised [Regulations on Orphan Drug Designation] (May 12, 2016).

6 items including 'Wellmacor Soft Cap. (Omega- 3-acid ethyl esters 90) are generic medicine of 'Omacor Soft Cap. (Omega- 3-acid ethylesters 90)' approved in 2005 and the effectiveness and efficacy are "prevention of secondary occurrence after myocardial infarction" and "dietary supplements to reduce elevated triglyceride levels in endogenous hyper triglyceridemia patients." The product is a generic medicine of prescription/ new drug and the bioequivalence test data was submitted in accordance with Article 4(1)③ of the Regulation on Safety of Medicinal Products, etc.

7 items including 'Laylon Tab' are generic drugs of 'LAYLA TAB.' approved in 2012 and their effectiveness and efficacy are mitigation of osteoarthritis symptom. The products submitted the data on comparative

dissolution test with comparator registered in the drug patent list in accordance with Article 3(1)② of Regulations on Item Approval on Herbal Medicine. etc. for review of safety and efficacy data.

15 items including 'Partislen S Tab' (Artemisia Herb 95% Ethanol Soft Ext. (20→1)) are generic medicine of 'Stillen 2X Tab. (Artemisia Herb 95% Ethanol Soft Ext. (20→1)' which was approved in 2015 and their effectivenes and efficacy are improvement of gastric mucosa (inflammation (erosion), bleeding, redness and edema) due to acute gastritis and chronic gastritis. The products submitted the data on comparative dissolution test with comparator registered in the drug patent list in accordance with Article 3(10)② of Regulations on Item Approval on Herbal Medicine. etc. for review of safety and efficacy data.

Table 45. Approval Status of Herbal Medicinal products as Prescription Drug in 2018

No.	Mfg/ Import	Product	Company	Date of approval	Code	Efficacy/Effectiveness
1	Mfg.	Wellmacor Soft Cap.	JW Shinyak	2018-03-23	[218] Atherosclerotic drug	1. Prevention of secondary occurrence after myocardial infarction 2. Dietary supplements to reduce elevated triglyceride levels in endogenous hyper triglyceridemia patients
2	Mfg.	Ajuco Soft Cap.	Aju Pharm	2018-04-18		
3	Mfg.	Megalow Soft Cap.	Sam Chun Dang Pharm.	2018-04-18		
4	Mfg.	Megatree Soft Cap.	Korea Arlico Pharm	2018-04-30		
5	Mfg.	Oma-TG Soft Cap.	Daewoong Bio	2018-04-30		
6	Mfg.	Omacan Soft Cap.	KyongBo Pharmaceutical	2018-04-30		
7	Import	Nexobrid Gel 5g	BL&H	2018-05-16	[269] Other drugs for outer skin	Removal of crusta from adults (more than 18 years old) due to deep second and third degree burns
8	Mfg.	Laylon Tab.	Dongkook Pharmaceutical	2018-05-14	[114] Antipyretics and analgesics, anti-inflammatory agents	Mitigation of osteoarthritis symptoms
9	Mfg.	Lylia Tab.	Daewoo Pharm.	2018-07-19		
10	Mfg.	Rayns Tab.	Korus Pharm.	2018-07-30		

11	Mfg.	Oshil Tab.	Wooridul Pharmaceutical	2018-08-21		
12	Mfg.	Lenabone Tab.	Dongkoo Bio & Pharma	2018-08-28		
13	Mfg.	New Rayla Tab.	Ahngook Newpharm	2018-08-28		
14	Mfg.	Osna Tab.	Eden Pharma	2018-09-07		
15	Mfg.	Partislen S Tab.	Richwood Trading	2018-11-09	[232] Peptic ulcer agent	1. Improvement of gastric mucosa of the following diseases (inflammation (erosion), bleeding, redness, edema) : Acute gastritis, chronic gastritis
16	Mfg.	Stil U 2X Tab.	Kukje Pharm	2018-11-12		
17	Mfg.	Asica 2X Tab.	Aju Pharm	2018-11-12		
18	Mfg.	Estlen-S Tab.	Samjin Pharm	2018-11-12		
19	Mfg.	NPiren S Tab.	Daehan New Pharm	2018-11-12		
20	Mfg.	Arcidine-F Tab.	Wooridul Pharmaceutical	2018-11-12		
21	Mfg.	Estalen 2X Tab.	Hana Pharm	2018-11-12		
22	Mfg.	BI-Tilin 2X Tab.	BINEX	2018-11-12		
23	Mfg.	Stelin 2X Tab.	Korea Arlico Pharm	2018-11-15		
24	Mfg.	Uparon F Tab.	Dongkook Pharmaceutical	2018-11-16		
25	Mfg.	Sutilen 2X Tab.	Youngil Pharm	2018-11-16		
26	Mfg.	Stoae 2X Tab.	Kolmar Korea	2018-11-16		
27	Mfg.	Bearen 2X Tab.	Daewoong Bio	2018-11-16		
28	Mfg.	Stillen 2X Tab.	Ilhwa	2018-11-27		
29	Mfg.	Nextil 2X Tab.	Nex Pharm Korea	2018-12-28		

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

4.2 Approval Status of Herbal Medicine as OTC drugs

The OTC drugs from herbal medicinal products approved in 2018 include 8 items of ' Mix extract" based on the Korean medicinal book, 1 item of 'Orbiox Natural Gel(Nohoei)' which was formulated with a new administration route (external use), and 1 item of Hetomacin Soft Ext.(Gupoonghaedoktang)' which was formulated as a new dosage form (soft extract) (Refer to Table 47).

8 items that have the same active ingredient of the mixed extract under Part III, Herbal Medicine Prescription of the Korean Herbal Pharmacopoeia(KHP) were approved for the herbal health insurance medicine in accordance with Article 15 and Article 16 of the Regulations on Item Approval on Herbal Medicinal Products, etc. For reference, the drugs for herbal health insurance medicine from the drugs developed as new dosage form including soft extract based on the herbal medicine prescriptions listed in the Korean medicine book were 39 items since 2015 (7 items in 2015, 9 items in 2016 and 8 items in 2018).

'Orbiox Natural Gel (Nohoei)' was an item which formulated the active ingredient (Nohoei) approved as an oral tablet into external use drug (gel) with a new administration route, but its classification was changed from medicine into medical device "medical lubricant" according to the revision of the Regulations on Medical Device Item and Item-Specific Class (Aug 11, 2016) and the approval conditions to change the classification into the medical device was imposed.

'Hetomacin Soft Ext. (Gupoonghaedoktang)' is a comparator of 'Hetomacin Cap. (Gupoonghaedoktang)', reviewed according to 'Drugs requiring data submission 9. Drugs with same administration route, but new dosage form (solid preparation for internal use (there is a case where all components were used as liquid drug) → liquid drug for internal use' and approved accordingly.

Table 46. Approval Status of Herbal Medicinal Products as OTC drugs in 2018

No.	Mfg/ Import	Product	Company	Date of approval	Efficacy/ Effectiveness	Remark
1	Mfg.	Hanpoong Gunghatang soft extract (mix extract)	Hanpoong Pharm Co. Ltd.	2018-04-10	For oriental health insurance	OTC
2	Mfg.	Hanpoong Banhabaekchul Cheonmatang soft extract (mix extract)	Hanpoong Pharm Co. Ltd	2018-04-23	For oriental health insurance	OTC
3	Mfg.	Hanpoong Galgeuntang soft extract (mix extract)	Hanpoong Pharm Co. Ltd	2018-04-24	For oriental health insurance	OTC
4	Mfg.	Orbiox Natural Gel (Nohoei)	Orbiox Qoltech	2018-04-27	Lubricants for inserting medical devices into the body orifice for medical purposes such as diagnosis or treatment	OTC

5	Mfg.	Kyongbang Daesihotang soft extract (mix extract)	Kyongbang Pharm.	2018-08-06	For oriental health insurance	OTC
6	Mfg.	Kyongbang Daehwajungeum Tab (mix extract)	Kyongbang Pharm.	2018-08-06	For oriental health insurance	OTC
7	Mfg.	Kyongbang Sigyeongbanhatang Tab (mix extract)	Kyongbang Pharm.	2018-08-06	For oriental health insurance	OTC
8	Mfg.	Kyongbang Palmooltang soft extract (mix extract)	Kyongbang Pharm.	2018-09-18	For oriental health insurance	OTC
9	Mfg.	Kyongbang Hyangsapyeongwisan soft extract (mix extract)	Kyongbang Pharm.	2018-09-28	For oriental health insurance	OTC
10	Mfg.	Hetomacin Soft Ext. (Gupoonghaedoktang	Jungwoo Medicines	2018-11-14	Sore throat (swollen throat) symptoms: Tonsillitis and periamygdalitis	OTC

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

4.3 Information on approval of Drug substances and Herbal substances

For drug substance, 2 items such as Borakdaehwanggamchotang dried extract (5→1) and Hanpooing Ssanghwatang soft extract(drug substance) and, for herbal substance, Saeromchanijacho were approved (Refer to Table 48).

Table 47. Approval Status of Herbal Medicinal Products in 2018 (Drug Substance and Herbal Substances)

No.	Mfg/ import/ imported	Product	Company	Date of approval	Efficacy/ Effects	Remarks
1	Mfg.	Borakdaehwanggamchotang dry extract (5→1)	Borak	2018-02-19	Other prescription drug	Drug substance
2	Mfg.	Hanpooing Ssanghwatang soft extract (Drug substance)	Hanpoong Pharm Co. Ltd	2018-11-16	Other prescription drug	Drug substance
3	Mfg.	Saeromchanijacho	Saerom Pharm	2018-01-18	Other prescription drug	Herbal substance

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

Appendix	**Information on departments responsible for pharmaceutical petitions, etc.**

Table 48. Information on departments responsible for pharmaceutical petitions, etc.

(As of May, 2019)

Item	Department	Medication Service
Innovative Convergence Products Support Department Approval Management Team		· Preliminary review and management related to drug review and approval · Approval of drugs for manufacturing and import (including changes) · Registration of DMF · Preliminary review and management related to biopharmaceuticals review and approval · Approval of biopharmaceuticals for manufacturing and import (including changes) · Preliminary review and management related to herbal medicines, etc. review and approval · Approval of herbal medicines, etc. for manufacturing and import (including changes) · Approval of quasi-drugs for manufacturing and import
Pharmaceutical Safety Bureau	Pharmaceutical Policy Division	· Designation of orphan drug
	Pharmaceutical Management Division	· Drug marking and labeling · Renewal of drugs
	Pharmaceutical Safety Evaluation Division	· Reevaluation and re-review of drugs · Risk management plan
	Pharmaceutical Quality Division	· GMP evaluation and guidance of drugs · Inspection of drug substance (DMF)
	Clinical Trials Management Division	· Approval of clinical protocols · Inspection of clinical trials · Control of clinical trial and non-clinical (GLP) institutionals
	Pharmaceutical Approval and Patent Management Division	· Listing and management of the patent lists · Management of patents linked to medical products (approval for priority sales items, etc.)

	Narcotics Policy Division		· Approval of drug mfg., import/ export and items · Quality control of narcotic drugs · Designation of temporary narcotics
	Narcotics Management Division		· Follow-up management of narcotics
NIFDS	Drug Evaluation Department	Drug Review Management Division	· Notification of pre-review
		Pharmaceutical Standardization Division	710 Drugs for prescription 731 Preservative 741 Capsules 799 Drugs not classified separately and not primarily used for treatment (those not containing safety and efficacy review) · Review of registration data for drug substances (excluding ingredients of new drugs) · Quality control of drug substances · Review of generic drug specification and test methods
		Cardiovascular and Neurology Products Division	110 Drugs for central nervous system 120 Drugs for peripheral nervous system 190 Other drugs for the nervous system out of drugs for other nervous systems and sensory organs 210 Drugs for circulatory systems 220 Respiratory System Drugs 264 Drugs for pain-relieving, antipruritic, convergence, anti-inflammatory 330 Drugs for blood and body fluids 799 Drugs not intended primarily for the treatment of other diseases (applicable to therapeutic class of cardiovascular and neurology products including safety and efficacy review and non-smoking adjuvant)

			800 Narcotics Review of registration data of drug substances in the code · Quality and safety/efficacy review · Review of clinical trial protocols · Preliminary review · Review of re-evaluation/re-review report
		Oncology and Antimicrobial Products Division	140 Allergy drugs 261 Disinfectant for outer skin 262 Wound protection agent 263 Drugs for purulent diseases 265 Drugs for parasitic skin disease 266 Skin softener (including caustic agent) 269 Other drugs for outer skin 410 Tissue resuscitation drug 420 Oncology drugs 430 for treatment and diagnosis of tissue cells 490 Functional medicines for other tissue cells 610 Antibiotic preparations 620 Chemotherapy drugs 640 Drugs for parasites 720 Drugs for diagnosis 739 Other public sanitary drugs 799 Drugs not classified separately and not primarily for therapeutic purposes (applicable to therapeutic class of oncology and antimicrobial products including safety and efficacy review) ※ When the efficacy and effectiveness are by antibacterial, antifungal, antiviral agent

			· Quality and safety/efficacy review · Review of clinical trial protocols · Preliminary review · Review of re-evaluation/re-review report
		Gastroenterology and Metabolism Products Division	130 Drugs for sensory organs 230 Drugs for digestive organs 240 Hormone drugs (including anti-hormonal agents) 250 Drugs for urogenital organs and anal 267 Drugs for hair (hair growth, hair loss and hair growth) 290 Other drugs for individual organs 310 Vitamins 320 Vital energy alterative 340 artificial perfusion drug 390 Other metabolic drugs 799 Medicines not classified separately and not primarily for therapeutic purposes (applicable to therapeutic class of gastroenterology and metabolism products including safety and efficacy review) · Review of registration data of drug substances applicable to the code (drug substance of new drug) · Quality and safety/efficacy review · Review of clinical trial protocols · Preliminary review · Review of re-evaluation/re-review report
		Bioequivalence Evaluation Division	· Review of biological equivalence test plan · Review of biological equivalence test result report review · Review of reliability assessment of biological equivalence test

			· Review of biological equivalence examination re-evaluation · Review of drug equivalency test result report review (including manufacturing (import) item approval/ notification) · Review of report of drug equivalence test result (approval/ report)
Biopharmaceuticals and Herbal Medicine Bureau	Biopharmaceutical Quality Management Division		· Biological preparations, manufacturing and import/export items, GMP evaluation and guidance · Inspection of drug substance of human placenta-derived drugs (DMF) · Re-review and re-evaluation of biopharmaceuticals · Risk Management Plan
	Herbal Medicine Policy Division		· Preliminary GMP evaluation for herbal medicine and herbal medicine
	Cosmetics Policy Division		· GMP evaluation such as cosmetics
	Quasi-Drug Policy Division		· Quasi-drug GMP evaluation
NIFDS	Biopharmaceuticals and Herbal Medicine Evaluation Department	Biopharmaceuticals Review Management Division	· Notification of pre-review
		Biologics Division	Biologics and human placenta-derived drugs · Quality and safety/efficacy review · Review of clinical trial plan · 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 plan · Preliminary review · Review of re-evaluation and 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/re-review result report
		Herbal Medicinal Products Division	· Quality and safety/ efficacy review · Review of drug equivalence (including bioequivalence test) · Review of clinical trial protocol · Pre-review · Review of re-evaluation/re-review result report
		Cosmetics Evaluation Division	· Review of functional cosmetics · Quasi-drugs · Safety/ efficacy review · Quality data review · Pre-review