

### Applications for Authorisation/Registration

Number of applications submitted and completed in the specific reporting month as well as open applications at the beginning of the year and at the end of each specific month

2019	01.01.	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total
<b>Total of completed applications (Parts 1 + 2 + 3)</b>	-	97	163	225	175	124	113	171	123	155	164			1.510
<b>Authorisation/Registration (Part 1)</b>	-	81	146	182	143	106	97	155	99	141	151			1.301
<b>Refusals (Part 2)</b>	-	1	0	12	3	2	1	5	1	1	0			26
<b>Withdrawals (Part 3)</b>	-	15	17	31	29	16	15	11	23	13	13			183
<b>Total of applications submitted</b>	-	79	100	201	147	185	138	159	118	137	149			1.413
<b>Total of open applications</b>	2.628	2.610	2.547	2.523	2.495	2.556	2.581	2.569	2.564	2.546	2.531			-

Data are determined on the 15. of the following month.



## Applications for Authorisation/Registration

Part 1 of 3: Share of authorisations/registrations of the total sum of completed applications

2019	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total
<b>Authorisations (Section 25 AMG)</b>	<b>78</b>	<b>146</b>	<b>182</b>	<b>129</b>	<b>102</b>	<b>97</b>	<b>150</b>	<b>83</b>	<b>123</b>	<b>144</b>			<b>1.234</b>
<b>New active substances in accordance with Section 48 sub-section 2 sentence 1 AMG</b>	<b>2</b>	<b>7</b>	<b>4</b>	<b>2</b>	<b>3</b>	<b>0</b>	<b>6</b>	<b>2</b>	<b>1</b>	<b>2</b>			<b>29</b>
Decentralised Procedures (DCP) - DE=RMS	0	4	0	0	0	0	0	0	1	0			5
Decentralised Procedures (DCP) - DE=CMS	0	0	0	0	0	0	1	0	0	2			3
Mutual Recognition Procedures (MRP)	0	3	0	1	0	0	0	0	0	0			4
National procedures	0	0	0	0	0	0	0	0	0	0			0
Phytotherapeutic medicinal products	0	0	0	0	0	0	0	0	0	0			0
Parallel imports	2	0	4	1	3	0	5	2	0	0			17
<b>Known active substances</b>	<b>76</b>	<b>139</b>	<b>178</b>	<b>127</b>	<b>99</b>	<b>97</b>	<b>144</b>	<b>81</b>	<b>122</b>	<b>142</b>			<b>1.205</b>
Decentralised Procedures (DCP) - DE=RMS	15	28	25	12	27	18	30	18	23	34			230
Decentralised Procedures (DCP) - DE=CMS	36	73	100	50	37	53	57	34	65	67			572
Mutual Recognition Procedures (MRP)	1	7	7	18	7	5	14	9	0	2			70
National procedures	11	13	26	20	8	3	6	2	6	8			103
Phytotherapeutic medicinal products	0	0	0	0	3	1	0	0	0	0			4
Anthroposophic/homoeopathic medicinal products	0	5	0	0	0	1	1	0	0	0			7
Parallel imports	13	13	20	27	17	16	36	18	28	31			219
<b>Registrations (Section 39 AMG)</b>	<b>3</b>	<b>0</b>	<b>0</b>	<b>4</b>	<b>3</b>	<b>0</b>	<b>1</b>	<b>2</b>	<b>2</b>	<b>2</b>			<b>17</b>
Registrations (Section 39 AMG)	0	0	0	1	0	0	0	0	0	1			2
Registrations (Section 39 a - d AMG)	2	0	0	2	3	0	1	2	2	1			13
Registrations (Section 39 a - d i.V.m. § 141(14) AMG)	1	0	0	1	0	0	0	0	0	0			2
<b>Authorisations under AMRadV (Section 1 sub-section 2 sentence 1 no. 4 AMRadV)</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>10</b>	<b>1</b>	<b>0</b>	<b>4</b>	<b>14</b>	<b>16</b>	<b>5</b>			<b>50</b>
<b>Total of completed applications (Part 1)</b>	<b>81</b>	<b>146</b>	<b>182</b>	<b>143</b>	<b>106</b>	<b>97</b>	<b>155</b>	<b>99</b>	<b>141</b>	<b>151</b>			<b>1.301</b>



## Applications for Authorisation/Registration

Part 2 of 3: Share of refusals of the total sum of completed applications

2019	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total
<b>Applications for authorisation (Section 25 AMG)</b>	<b>0</b>	<b>0</b>	<b>12</b>	<b>2</b>	<b>2</b>	<b>1</b>	<b>5</b>	<b>1</b>	<b>1</b>	<b>0</b>			<b>24</b>
<b>New active substances in accordance with Section 48 sub-section 2 sentence 1 AMG</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>			<b>0</b>
Decentralised Procedures (DCP) - DE=RMS	0	0	0	0	0	0	0	0	0	0			0
Decentralised Procedures (DCP) - DE=CMS	0	0	0	0	0	0	0	0	0	0			0
Mutual Recognition Procedures (MRP)	0	0	0	0	0	0	0	0	0	0			0
National procedures	0	0	0	0	0	0	0	0	0	0			0
Phytotherapeutic medicinal products	0	0	0	0	0	0	0	0	0	0			0
Parallel imports	0	0	0	0	0	0	0	0	0	0			0
<b>Known active substances</b>	<b>0</b>	<b>0</b>	<b>12</b>	<b>2</b>	<b>2</b>	<b>1</b>	<b>5</b>	<b>1</b>	<b>1</b>	<b>0</b>			<b>24</b>
Decentralised Procedures (DCP) - DE=RMS	0	0	0	2	0	1	0	0	0	0			3
Decentralised Procedures (DCP) - DE=CMS	0	0	6	0	0	0	1	0	0	0			7
Mutual Recognition Procedures (MRP)	0	0	0	0	0	0	0	0	0	0			0
National procedures	0	0	6	0	0	0	1	1	0	0			8
Phytotherapeutic medicinal products	0	0	0	0	0	0	2	0	0	0			2
Anthroposophic/homoeopathic medicinal products	0	0	0	0	0	0	1	0	1	0			2
Parallel imports	0	0	0	0	2	0	0	0	0	0			2
<b>Applications for registration (Section 39 AMG)</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>			<b>2</b>
Registrations (Section 39 AMG)	0	0	0	0	0	0	0	0	0	0			0
Registrations (Section 39 a - d AMG)	0	0	0	1	0	0	0	0	0	0			1
Registrations (Section 39 a - d i.V.m. § 141(14) AMG)	1	0	0	0	0	0	0	0	0	0			1
<b>Applications under AMRadV (Section 1 sub-section 2 sentence 1 no. 4 AMRadV)</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>			<b>0</b>
<b>Total of completed applications (Part 2)</b>	<b>1</b>	<b>0</b>	<b>12</b>	<b>3</b>	<b>2</b>	<b>1</b>	<b>5</b>	<b>1</b>	<b>1</b>	<b>0</b>			<b>26</b>

## Applications for Authorisation/Registration

Part 3 of 3: Share of refusals (according to general procedural principles) of the total sum of completed applications

2019	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total
<b>Applications for authorisation (Section 25 AMG)</b>	<b>14</b>	<b>16</b>	<b>31</b>	<b>29</b>	<b>16</b>	<b>15</b>	<b>11</b>	<b>23</b>	<b>13</b>	<b>13</b>			<b>181</b>
<b>New active substances in accordance with Section 48 sub-section 2 sentence 1 AMG</b>	<b>1</b>	<b>0</b>	<b>5</b>	<b>2</b>	<b>0</b>	<b>2</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>0</b>			<b>11</b>
Decentralised Procedures (DCP) - DE=RMS	0	0	4	0	0	0	0	0	0	0			4
Decentralised Procedures (DCP) - DE=CMS	1	0	1	2	0	2	0	0	1	0			7
Mutual Recognition Procedures (MRP)	0	0	0	0	0	0	0	0	0	0			0
National procedures	0	0	0	0	0	0	0	0	0	0			0
Phytotherapeutic medicinal products	0	0	0	0	0	0	0	0	0	0			0
Parallel imports	0	0	0	0	0	0	0	0	0	0			0
<b>Known active substances</b>	<b>13</b>	<b>16</b>	<b>26</b>	<b>27</b>	<b>16</b>	<b>13</b>	<b>11</b>	<b>23</b>	<b>12</b>	<b>13</b>			<b>170</b>
Decentralised Procedures (DCP) - DE=RMS	3	5	10	5	1	6	3	12	8	1			54
Decentralised Procedures (DCP) - DE=CMS	6	6	15	6	13	4	5	6	2	8			71
Mutual Recognition Procedures (MRP)	3	0	0	0	2	0	0	0	0	0			5
National procedures	0	0	1	3	0	3	0	0	0	1			8
Phytotherapeutic medicinal products	0	0	0	0	0	0	1	0	0	0			1
Anthroposophic/homoeopathic medicinal products	1	1	0	0	0	0	0	0	0	0			2
Parallel imports	0	4	0	13	0	0	2	5	2	3			29
<b>Applications for registration (Section 39 AMG)</b>	<b>1</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>			<b>2</b>
Registrations (Section 39 AMG)	0	0	0	0	0	0	0	0	0	0			0
Registrations (Section 39 a - d AMG)	1	1	0	0	0	0	0	0	0	0			2
Registrations (Section 39 a - d i.V.m. § 141(14) AMG)	0	0	0	0	0	0	0	0	0	0			0
<b>Applications under AMRadV (Section 1 sub-section 2 sentence 1 no. 4 AMRadV)</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>			<b>0</b>
<b>Total of completed applications (Part 3)</b>	<b>15</b>	<b>17</b>	<b>31</b>	<b>29</b>	<b>16</b>	<b>15</b>	<b>11</b>	<b>23</b>	<b>13</b>	<b>13</b>			<b>183</b>



## Applications for Authorisation/Registration

Number of submitted applications

2019	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total
<b>Applications for authorisation (Section 21 AMG)</b>	<b>79</b>	<b>88</b>	<b>198</b>	<b>144</b>	<b>183</b>	<b>126</b>	<b>140</b>	<b>108</b>	<b>137</b>	<b>133</b>			<b>1.336</b>
<b>New active substances in accordance with Section 48 sub-section 2 sentence 1 AMG</b>	<b>3</b>	<b>0</b>	<b>29</b>	<b>10</b>	<b>50</b>	<b>15</b>	<b>8</b>	<b>3</b>	<b>25</b>	<b>12</b>			<b>155</b>
Decentralised Procedures (DCP) - DE=RMS	0	0	17	5	42	3	0	0	6	8			81
Decentralised Procedures (DCP) - DE=CMS	1	0	9	4	7	9	4	3	16	4			57
Mutual Recognition Procedures (MRP)	0	0	0	0	0	0	0	0	0	0			0
National procedures	0	0	0	0	0	0	0	0	1	0			1
Phytotherapeutic medicinal products	0	0	0	0	0	0	0	0	0	0			0
Parallel imports	2	0	3	1	1	3	4	0	2	0			16
<b>Known active substances</b>	<b>76</b>	<b>88</b>	<b>169</b>	<b>134</b>	<b>133</b>	<b>111</b>	<b>132</b>	<b>105</b>	<b>112</b>	<b>121</b>			<b>1.181</b>
Decentralised Procedures (DCP) - DE=RMS	12	18	51	34	54	25	21	15	21	41			292
Decentralised Procedures (DCP) - DE=CMS	18	28	86	37	30	51	52	36	45	45			428
Mutual Recognition Procedures (MRP)	1	1	4	1	11	5	0	3	12	2			40
National procedures	10	8	8	20	8	5	18	22	6	6			111
Phytotherapeutic medicinal products	0	1	2	0	0	1	0	0	0	0			4
Anthroposophic/homoeopathic medicinal products	0	0	1	1	0	0	0	0	4	1			7
Parallel imports	35	32	17	41	30	24	41	29	24	26			299
<b>Applications for registration (Sections 38/39 AMG)</b>	<b>0</b>	<b>8</b>	<b>3</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>3</b>	<b>0</b>	<b>0</b>	<b>0</b>			<b>20</b>
Registrations (Section 39 AMG)	0	6	2	1	0	1	1	0	0	0			11
Registrations (Section 39 a - d AMG)	0	2	1	0	2	2	2	0	0	0			9
Registrations (Section 39 a - d i.V.m. § 141(14) AMG)	0	0	0	0	0	0	0	0	0	0			0
<b>Applications under AMRadV (Section 1 sub-section 2 sentence 1 no. 4 AMRadV)</b>	<b>0</b>	<b>4</b>	<b>0</b>	<b>2</b>	<b>0</b>	<b>9</b>	<b>16</b>	<b>10</b>	<b>0</b>	<b>16</b>			<b>57</b>
<b>Total of applications submitted</b>	<b>79</b>	<b>100</b>	<b>201</b>	<b>147</b>	<b>185</b>	<b>138</b>	<b>159</b>	<b>118</b>	<b>137</b>	<b>149</b>			<b>1.413</b>



## Applications for Authorisation/Registration

Open applications per type of application/sub-application at the beginning of the year and at the end of each specific month

2019	01.01.19	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
<b>Applications for authorisation (Section 21 AMG)</b>	<b>2.580</b>	<b>2.567</b>	<b>2.493</b>	<b>2.466</b>	<b>2.450</b>	<b>2.513</b>	<b>2.526</b>	<b>2.500</b>	<b>2.501</b>	<b>2.501</b>	<b>2.477</b>		
<b>New active substances in accordance with Section 48 sub-section 2 sentence 1 AMG</b>	<b>239</b>	<b>239</b>	<b>232</b>	<b>252</b>	<b>258</b>	<b>305</b>	<b>318</b>	<b>320</b>	<b>321</b>	<b>344</b>	<b>354</b>		
Decentralised Procedures (DCP) - DE=RMS	76	76	72	85	90	132	135	135	135	140	148		
Decentralised Procedures (DCP) - DE=CMS	135	135	135	143	145	152	159	162	165	180	182		
Mutual Recognition Procedures (MRP)	4	4	1	1	0	0	0	0	0	0	0		
National procedures	2	2	2	2	2	2	2	2	2	3	3		
Phytotherapeutic medicinal products	0	0	0	0	0	0	0	0	0	0	0		
Parallel imports	22	22	22	21	21	19	22	21	19	21	21		
<b>Known active substances</b>	<b>2.341</b>	<b>2.328</b>	<b>2.261</b>	<b>2.214</b>	<b>2.192</b>	<b>2.208</b>	<b>2.208</b>	<b>2.180</b>	<b>2.180</b>	<b>2.157</b>	<b>2.123</b>		
Decentralised Procedures (DCP) - DE=RMS	612	606	591	607	622	648	648	636	621	611	617		
Decentralised Procedures (DCP) - DE=CMS	1.063	1.039	988	953	934	914	908	897	893	871	841		
Mutual Recognition Procedures (MRP)	80	77	71	68	51	53	53	39	33	45	45		
National procedures	151	150	145	120	117	117	116	127	146	146	143		
Phytotherapeutic medicinal products	18	18	19	21	21	18	18	15	15	15	15		
Anthroposophic/homoeopathic medicinal products	14	13	7	8	9	9	8	6	6	9	10		
Parallel imports	403	425	440	437	438	449	457	460	466	460	452		
<b>Applications for registration (Sections 38/39 AMG)</b>	<b>43</b>	<b>38</b>	<b>45</b>	<b>48</b>	<b>44</b>	<b>43</b>	<b>46</b>	<b>48</b>	<b>46</b>	<b>44</b>	<b>42</b>		
Registrations (Section 39 AMG)	4	4	10	12	12	12	13	14	14	14	13		
Registrations (Section 39 a - d AMG)	32	29	30	31	28	27	29	30	28	26	25		
Registrations (Section 39 a - d i.V.m. § 141(14) AMG)	7	5	5	5	4	4	4	4	4	4	4		
<b>Applications under AMRadV (Section 1 sub-section 2 sentence 1 no. 4 AMRadV)</b>	<b>5</b>	<b>5</b>	<b>9</b>	<b>9</b>	<b>1</b>	<b>0</b>	<b>9</b>	<b>21</b>	<b>17</b>	<b>1</b>	<b>12</b>		
<b>Total of open applications</b>	<b>2.628</b>	<b>2.610</b>	<b>2.547</b>	<b>2.523</b>	<b>2.495</b>	<b>2.556</b>	<b>2.581</b>	<b>2.569</b>	<b>2.564</b>	<b>2.546</b>	<b>2.531</b>		



## Renewals according to sections 31, 39 and 39c AMG

2019	Total open as of 1 Jan 2019 <sup>2</sup>	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total Submissions/ Completions <sup>3</sup>
<b>Applications vor renewal (submitted applications)<sup>1</sup></b>		<b>155</b>	<b>119</b>	<b>62</b>	<b>80</b>	<b>96</b>	<b>120</b>	<b>90</b>	<b>132</b>	<b>109</b>	<b>190</b>			<b>1.153</b>
a) Authorisations (Section 31 AMG)		152	119	61	76	95	113	86	130	108	180			<b>1.120</b>
b) Registrations (Section 39 / Section 39c AMG)		3	0	1	4	1	7	4	2	1	10			<b>33</b>
<b>Positive renewal decisions<sup>1</sup></b>		<b>135</b>	<b>113</b>	<b>190</b>	<b>243</b>	<b>148</b>	<b>77</b>	<b>53</b>	<b>95</b>	<b>104</b>	<b>98</b>			<b>1.256</b>
a) Authorisations (Section 31 AMG)		131	109	186	225	140	69	48	88	102	96			<b>1.194</b>
b) Registrations (Section 39 / Section 39c AMG)		4	4	4	18	8	8	5	7	2	2			<b>62</b>
<b>Refusals (not yet legally binding)<sup>1</sup></b>		<b>6</b>	<b>0</b>	<b>2</b>	<b>1</b>	<b>4</b>	<b>1</b>	<b>4</b>	<b>0</b>	<b>0</b>	<b>11</b>			<b>29</b>
a) Authorisations (Section 31 AMG)		6	0	2	1	4	1	4	0	0	11			<b>29</b>
b) Registrations (Section 39 / Section 39c AMG)		0	0	0	0	0	0	0	0	0	0			<b>0</b>
<b>Deletions (Section 31 sub-section 1 No. 2-4 AMG)<sup>1</sup></b>		<b>18</b>	<b>75</b>	<b>53</b>	<b>35</b>	<b>51</b>	<b>33</b>	<b>14</b>	<b>15</b>	<b>44</b>	<b>10</b>			<b>348</b>
a) Authorisations (Section 31 AMG)		18	75	53	35	51	33	14	15	44	10			<b>348</b>
b) Registrations (Section 39 / Section 39c AMG)		0	0	0	0	0	0	0	0	0	0			<b>0</b>
<b>Total of completed procedures<sup>1</sup></b>		<b>159</b>	<b>188</b>	<b>245</b>	<b>279</b>	<b>203</b>	<b>111</b>	<b>71</b>	<b>110</b>	<b>148</b>	<b>119</b>			<b>1.633</b>
a) Authorisations (Section 31 AMG)		155	184	241	261	195	103	66	103	146	117			<b>1.571</b>
b) Registrations (Section 39 / Section 39c AMG)		4	4	4	18	8	8	5	7	2	2			<b>62</b>
<b>Total of open applications<sup>4</sup></b>	<b>1.636</b>	<b>1.594</b>	<b>1.564</b>	<b>1.414</b>	<b>1.412</b>	<b>1.393</b>	<b>1.377</b>	<b>1.350</b>	<b>1.360</b>	<b>1.355</b>	<b>1.343</b>			
a) Authorisations (Section 31 AMG)	1.532	1.488	1.455	1.319	1.325	1.311	1.298	1.280	1.290	1.279	1.272			
b) Registrations (Section 39 / Section 39c AMG)	104	106	109	95	87	82	79	70	70	76	71			

The data are determined on the 15th of the following month.

<sup>1</sup> Figures are determined for each month on a daily basis

<sup>2</sup> Reference date: 01 January 2019

<sup>3</sup> Cut-off date: End of the respective reporting month

<sup>4</sup> if several applications are open for one medicinal product, only one application is counted