zugelassene Humanarzneispezialitäten

Arzneimittel-Kategorie	Antragskategorie/Art der ASp bei Zulassung bzw. entsprechende Antragskategorie	Anzahl
Biologische Arzneimittel	Full application (Article 8(3) of Directive No 2001/83/EC)	298
	Generic application (Article 10(1) of Directive No 2001/83/EC)	3
	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	17
	Well-established use application (Article 10a of Directive No 2001/83/EC)	37
Homöopathika	Homeopathic marketing authorisation procedure (Article 16 of Directive No 2001/83/EC)	518
Medizinische Gase	Generic application (Article 10(1) of Directive No 2001/83/EC)	1
	Well-established use application (Article 10a of Directive No 2001/83/EC)	40
Pflanzliche Arzneimittel	Fixed combination application (Article 10b of Directive No 2001/83/EC)	2
	Full application (Article 8(3) of Directive No 2001/83/EC)	57
	Generic application (Article 10(1) of Directive No 2001/83/EC)	4
	Well-established use application (Article 10a of Directive No 2001/83/EC)	96
Radiopharmazeutika	Full application (Article 8(3) of Directive No 2001/83/EC)	17
	Generic application (Article 10(1) of Directive No 2001/83/EC)	11
	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	3
	Well-established use application (Article 10a of Directive No 2001/83/EC)	15
Chemische Arzneimittel	Fixed combination application (Article 10b of Directive No 2001/83/EC)	263
	Full application (Article 8(3) of Directive No 2001/83/EC)	1.520
	Generic application (Article 10(1) of Directive No 2001/83/EC)	4.824
	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	694
	Informed consent application (Article 10c of Directive No 2001/83/EC)	27
	Well-established use application (Article 10a of Directive No 2001/83/EC)	910
	Gesamt	**9.357**

registrierte Humanarzneispezialitäten

Arzneimittel-Kategorie	Antragskategorie/Art der ASp bei Registrierung bzw. entsprechende Antragskategorie	Anzahl
Allergenherstellverfahren	Allergenherstellverfahren	163
Apothekeneigene	Apothekeneigene Registrierung	605
Homöopathika	Simplified registration application for a homeopathic medicinal product (Article 14 of Directive No 2001/83/EC)	1.905
Traditionelle pflanzliche Registrierungen	Traditional use registration for herbal medicinal product application (Article 16a of Directive No 2001/83/EC)	211
	Gesamt	**2.884**

zugelassene Veterinärarzneispezialitäten

Arzneimittel-Kategorie	Antragskategorie/Art der ASp bei Zulassung bzw. entsprechende Antragskategorie	Anzahl
Biologische Arzneimittel	Applications in exceptional circumstances (Article 25 of Regulation (EU) 2019/6)	1
	Full application (Article 12(3) of Directive No 2001/82/EC)	127
	Full application - known active substance (Article 8 of Regulation (EU) 2019/6)	11
	Fixed combination application (Article 13b of Directive No 2001/82/EC)	1
	Generic application (Article 13(1) of Directive No 2001/82/EC)	2
	Hybrid application – bioavailability studies cannot be used to demonstrate bioequivalence (Article 19(1)(b) of Regulation (EU) 2019/6)	1
	Immunological veterinary medicinal product application (Article 13d of Directive No 2001/82/EC)	10
	Informed consent application (Article 13c of Directive No 2001/82/EC)	1
	Similar biological application (Article 13(4) of Directive No 2001/82/EC)	2
Fütterungsarzneimittel-Vormischungen	Bibliographic application (Article 22 of Regulation (EU) 2019/6)	1
	Full application (Article 12(3) of Directive No 2001/82/EC)	5
	Generic application (Article 13(1) of Directive No 2001/82/EC)	7
	Hybrid application (Article 13(3) of Directive No 2001/82/EC)	2
Homöopathika	Homeopathic marketing authorisation procedure (Article 19 of Directive No 2001/82/EC)	154
Pflanzliche Arzneimittel	Full application (Article 12(3) of Directive No 2001/82/EC)	1
Chemische Arzneimittel	Applications for limited markets (Article 23 of Regulation (EU) 2019/6)	1
	Bibliographic application (Article 22 of Regulation (EU) 2019/6)	8
	Fixed combination application (Article 13b of Directive No 2001/82/EC)	42
	Full application (Article 12(3) of Directive No 2001/82/EC)	299
	Full application - known active substance (Article 8 of Regulation (EU) 2019/6)	8
	Generic application (Article 18 of Regulation (EU) 2019/6)	63
	Generic application (Article 13(1) of Directive No 2001/82/EC)	504
	Hybrid application – bioavailability studies cannot be used to demonstrate bioequivalence (Article 19(1)(b) of Regulation (EU) 2019/6)	15
	Hybrid application – change in strength (Article 19(1)(a) of Regulation (EU) 2019/6)	27
	Hybrid application - other (Article 19(1)(a) of Regulation (EU) 2019/6)	2
	Hybrid application (Article 13(3) of Directive No 2001/82/EC)	221
	Hybrid application (Article 19(1) of Regulation (EU) 2019/6)	12
	Informed consent application (Article 13c of Directive No 2001/82/EC)	9
	Informed Consent application (Article 21 of Regulation (EU) 2019/6)	4
	Well-established use application (Article 13a of Directive No 2001/82/EC)	86
	Gesamt	**1.627**

	weitere Angaben für 2025	Anzahl
	Humanarzneispezialitäten-Zulassungen	490
	Aufhebungen von zugelassenen Humanarzneispezialitäten	443
	Veterinärarzneispezialitäten-Zulassungen	53
	Aufhebungen von zugelassenen Veterinärarzneispezialitäten	51
	Zugelassene Humanarzneispezialitäten zur rezeptfreien Abgabe (Gesamt)	1.249
Stand	Registrierte Humanarzneispezialitäten zur rezeptfreien Abgabe (Gesamt)	2.721
	Arzneispezialitäten mit Genehmigungen für den Vertrieb im Parallelimport (Gesamt)	486