## 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) | 304 |
| | 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) | 521 |
| 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) | 58 |
| | Generic application (Article 10(1) of Directive No 2001/83/EC) | 3 |
| | Well-established use application (Article 10a of Directive No 2001/83/EC) | 98 |
| Radiopharmazeutika | Full application (Article 8(3) of Directive No 2001/83/EC) | 18 |
| | 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) | 16 |
| Chemische Arzneimittel | Fixed combination application (Article 10b of Directive No 2001/83/EC) | 275 |
| | Full application (Article 8(3) of Directive No 2001/83/EC) | 1.597 |
| | Generic application (Article 10(1) of Directive No 2001/83/EC) | 4.725 |
| | Hybrid application (Article 10(3) of Directive No 2001/83/EC) | 653 |
| | Informed consent application (Article 10c of Directive No 2001/83/EC) | 27 |
| | Well-established use application (Article 10a of Directive No 2001/83/EC) | 901 |
| | **Gesamt** | **9.310** |

## registrierte Humanarzneispezialitäten

| Arzneimittel-Kategorie | Antragskategorie/Art der ASp bei Registrierung bzw. entsprechende Antragskategorie | Anzahl |
|---|---|---|
| Allergenherstellverfahren | Allergenherstellverfahren | 162 |
| Apothekeneigene | Apothekeneigene Registrierung | 621 |
| Homöopathika | Homeopathic simplified registration procedure (Article 14 of Directive No 2001/83/EC) | 1.974 |
| Traditionelle pflanzliche Registrierungen | Traditional use registration for herbal medicinal product application (Article 16a of Directive No 2001/83/EC) | 211 |
| | **Gesamt** | **2.968** |

## zugelassene Veterinärarzneispezialitäten

| Arzneimittel-Kategorie | Antragskategorie/Art der ASp bei Zulassung bzw. entsprechende Antragskategorie | Anzahl |
|---|---|---|
| Biologische Arzneimittel | Full application (Article 12(3) of Directive No 2001/82/EC) | 132 |
| | Full application - known active substance (Article 8 of Regulation (EU) 2019/6) | 3 |
| | Fixed combination application (Article 13b of Directive No 2001/82/EC) | 1 |
| | Generic application (Article 13(1) of Directive No 2001/82/EC) | 2 |
| | 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 | Full application (Article 12(3) of Directive No 2001/82/EC) | 7 |
| | Generic application (Article 13(1) of Directive No 2001/82/EC) | 7 |
| | Hybrid application (Article 13(3) of Directive No 2001/82/EC) | 2 |
| | Well-established use application (Article 13a 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 | Bibliographic application (Article 22 of Regulation (EU) 2019/6) | 1 |
| | Fixed combination application (Article 13b of Directive No 2001/82/EC) | 45 |
| | Full application (Article 12(3) of Directive No 2001/82/EC) | 315 |
| | Full application - known active substance (Article 8 of Regulation (EU) 2019/6) | 6 |
| | Generic application (Article 18 of Regulation (EU) 2019/6) | 42 |
| | Generic application (Article 13(1) of Directive No 2001/82/EC) | 518 |
| | Hybrid application – bioavailability studies cannot be used to demonstrate bioequivalence (Article 19(1)(b) of Re | 10 |
| | Hybrid application – change in strength (Article 19(1)(a) of Regulation (EU) 2019/6) | 22 |
| | Hybrid application - other (Article 19(1)(a) of Regulation (EU) 2019/6) | 2 |
| | Hybrid application (Article 13(3) of Directive No 2001/82/EC) | 225 |
| | Hybrid application (Article 19(1) of Regulation (EU) 2019/6) | 11 |
| | 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) | 91 |
| | **Gesamt** | **1.625** |

| | weitere Angaben für 2024 | Anzahl |
|---|---|---|
| | Humanarzneispezialitäten-Zulassungen | 505 |
| | Aufhebungen von zugelassenen Humanarzneispezialitäten | 418 |
| | Veterinärarzneispezialitäten-Zulassungen | 69 |
| | Aufhebungen von zugelassenen Veterinärarzneispezialitäten | 48 |
| | | |
| | Zugelassene Humanarzneispezialitäten zur rezeptfreien Abgabe (Gesamt) | 1.245 |
| Stand | Registrierte Humanarzneispezialitäten zur rezeptfreien Abgabe (Gesamt) | 2.806 |
| | Arzneispezialitäten mit Genehmigungen für den Vertrieb im Parallelimport (Gesamt) | 475 |