*This is a translation of the Danish fee list. In case of any discrepancies, the Danish text takes precedence.*

Fees payable for applications for a new marketing authorisation, registration, extension and renewal and annual

fees for medicinal products

The *Delimitation* column refers, if relevant, to the relevant articles of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use and Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of application** | **Type of medicinal product** | **Procedure – Denmark’s role** | **Delimitation** | **Danish Medicines Agency’s item number** | **Fee** |
| **New marketing authorisation and extensions** | Ordinary medicinal products and vitamin/mineral preparations | National | Fully documented application (art. 8.3/8, 23, 25) | 3001 | DKK 376,889 |
| Fixed combination medicinal products (art. 10b/20) | 3002 | DKK 376,889 |
| Bibliographicapplications (art. 10a/22) | 3003 | DKK 331,123 |
| Hybrid application (art. 10.3/19) with clinical studies concerning efficacy and/or safety. | 3004 | DKK 331,123 |
| Application concerning biological medicinal product analogous to already authorised medicinal products (art. 10.4). | 3005 | DKK 331,123 |
| Application concerning vitamin and mineral preparations, cf. the executive order on vitamin and mineral preparations | 3006 | DKK 331,123 |
| Hybrid application (art. 10.3/19) without clinical studies concerning efficacy and/or safety | 3007 | DKK 219,490 |
| Generics – veterinary, antibiotics (art. 18) | 3008 | DKK 219,490 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  |  | Generics – human (art. 10.1) | 3009 | DKK 218,333 |
| Generics – veterinary, non-antibiotics (art. 18) | 3010 | DKK 218,333 |
| Duplicate with same timetable as application subject to a full fee | 3011 | DKK 66,156 |
| Parallel registration (art. 10c/21) | 3012 | DKK 77,135 |
| Additional fee for assessment in addition to standard procedure due to complexity or the like of the submitted documentation | 3013 | DKK 49,128 |
| Future extension of marketing authorisation | 3014 | DKK 208,963 |
| Assessment of PSUR. One fee per D.sp.no. | 4001 | DKK 9,224 |
| DCP, RMS | Fully documented application (art. 8.3/8, 23, 25) | 3015 | DKK 436,575 |
| Fixed combination medicinal products (art. 10b/20) | 3016 | DKK 436,575 |
| Bibliographic application (art. 10a/22) | 3017 | DKK 429,317 |
| Hybrid application (art. 10.3/19) with clinical studies concerning efficacy and/or safety. | 3018 | DKK 429,317 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  |  | Application concerning biological medicinal product analogous to already authorised medicinal products (art. 10.4). | 3019 | DKK 429,317 |
| Hybrid application (art. 10.3/19) without clinical studies concerning efficacy and/or safety | 3020 | DKK 280,472 |
| Generics – veterinary, antibiotics (art. 18) | 3021 | DKK 279,465 |
| Generics – human (art. 10.1) | 3022 | DKK 278,019 |
| Generics – veterinary, non-antibiotics (art. 18) | 3023 | DKK 278,019 |
| Duplicate with same timetable as application subject to a full fee | 3024 | DKK 87,126 |
| Parallel registration (art. 10c/21) | 3025 | DKK 85,362 |
| Additional fee for assessment in addition to standard procedure due to complexity or the like of the submitted documentation | 3026 | DKK 57,650 |
| DCP/MRP, RMs | Future extension of marketing authorisation | 3027 | DKK 239,072 |
| Assessment of PSUR. One fee per D.sp.no. | 4002 | DKK 9,224 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  | DCP/MRP, CMS | All applications for new marketing authorisation | 3028/3029 | DKK 38,897 |
| Additional fee for assessment in addition to standard procedure due to complexity or the like of the submitted documentation | 3030 | DKK 5,403 |
| Future extension of marketing authorisation | 3031 | DKK 22,574 |
| New marketing authorisation, registration and extension | Herbal medicinal products, traditional herbal medicinal products or homeopathic medicinal products | National |  | 3032 | DKK 134,534 |
| DCP, RMS |  | 3033 | DKK 127,204 |
| DCP/MRP, CMS |  | 3034 | DKK 37,439 |
| All procedures | Assessment of periodic safety update report (PSUR). One fee per D.sp.no. | 4003 | DKK 9,224 |
| All procedures | Additional fee for assessment in addition to standard procedure due to complexity or the like of the submitted documentation | 3035 | DKK 49,128 |
| New marketing authorisation, registration and extension | All types | MRP/DCP/Natio nal, all roles | Rejection of new application for marketing authorisation upon regulatory validation | 3036 | DKK 28,696 |
| New marketing authorisation | All types | Parallel import and parallel trade | Per exporting country | 3037 | DKK 11,412 |
| New mutual recognition procedure, MRP | All types | MRP, RMS | Full procedure, incl. updating | 3038 | DKK 162,669 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  |  | Full procedure, incl. administrative updating | 3039 | DKK 63,194 |
| Day Zero procedure | 3040 | DKK 17,308 |
| Renewal of marketingauthorisation/registration | Ordinary medicinalproducts andvitamin/mineralpreparations | National |  | 3041 | DKK 6,803 |
| MRP, CMS |  | 3042 | DKK 1,742 |
| MRP, RMS |  | 3043 | DKK 11,123 |
| All types | Parallel import | One fee per D.sp.no. | 3044 | DKK 2,689 |
| Herbal medicinal products, traditionalherbal medicinalproducts andhomeopathicmedicinal products | National |  | 3045 | DKK 10,933 |
| Annual fee for medicinal products(general regulatoryfunctions, supervision, control and analysis) | All types | All procedures | A fee per MA number/drug ID | 3046 | DKK 20,863 |

 Fees for variations – human medicinal products

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of application** | **Field** | **Procedure – Denmark’s role** | **Delimitation** | **Danish Medicines Agency’s item number** | **Fee** |
| **Single** | Administrative and all types of IA and IAIN variations | National | Type IA, type IB and type II | 3101 | DKK 2,393 |
| MRP-RMS | Type IA, type IB and type II | 3102 | DKK 7,755 |
| MRP-CMS | Type IA, type IB and type II | 3103 | DKK 1,754 |
| Quality | National | Type IB and type II, simple | 3104 | DKK 12,088 |
| Type IB and type II, complex | 3105 | DKK 45,279 |
| MRP-RMS | Type IB and type II, simple | 3106 | DKK 18,854 |
| Type IB and type II, complex | 3107 | DKK 51,314 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  | MRP-CMS | Type IB and type II, simple | 3108 | DKK 1,754 |
| Type IB and type II, complex | 3109 | DKK 1,754 |
| Regulatory/clinical | National | Type IB | 3110 | DKK 9,393 |
| Type II variations | 3111 | DKK 23,394 |
| MRP-RMS | Type IB | 3112 | DKK 10,220 |
| Type II variations | 3113 | DKK 18,081 |
| MRP-CMS | Type IB and type II | 3114 | DKK 5,468 |
| **Grouping and worksharing** | Administrative and all types of IA and IAIN variations | National | Type IA, one D.sp.no. | 3115 | DKK 2,919 |
| Type IA, several D.sp.nos. | 3116 | DKK 3,708 |
| MRP-RMS | Type IA, one D.sp.no. | 3117 | DKK 9,874 |
| Type IA, several D.sp.nos. | 3118 | DKK 13,049 |
| Type IA, super grouping | 3119 | DKK 18,934 |
| MRP-CMS | Type IA, one D.sp.no. | 3120 | DKK 2,280 |
| Type IA, several D.sp.nos. | 3121 | DKK 3,071 |
| Quality | National | Type IB and type II, simple | 3122 | DKK 25,173 |
| Type IB and type II, complex | 3123 | DKK 50,734 |
| MRP-RMS | Type IB and type II, simple | 3124 | DKK 32,048 |
| Type IB and type II, complex | 3125 | DKK 59,526 |
| MRP, reference authority in case of worksharing | Type IB and type II, simple | 3126 | DKK 47,695 |
| Type IB and type II, complex | 3127 | DKK 93,344 |
| MRP-CMS | Type IB and type II, simple | 3128/3129 | DKK 3,071 |
| Type IB and type II, complex | 3130/3131 | DKK 6,217 |
| Regulatory/clinical | National | Type IB | 3132 | DKK 16,031 |
| Type II variations | 3133 | DKK 28,824 |
| MRP-RMS | Type IB | 3134 | DKK 16,084 |
| Type II variations | 3135 | DKK 27,882 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  | MRP, reference authority in case of worksharing | Type IB | 3136 | DKK 37,602 |
| Type II variations | 3137 | DKK 45,008 |
| MRP-CMS | Type IB and type II | 3138/3139 | DKK 8,622 |

 Fees for variations – veterinary medicinal products

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of application** | **Field** | **Procedure** | **Delimitation** | **Danish Medicines Agency’s item number** | **Fee** |
| Single | VNRAadministrative and regulatory | National | VNRA administrative | 3401 | DKK 2,762  |
| VNRA regulatory | 3402 | DKK 6,804 |
| MRP-RMS | VNRA administrative | 3403 | DKK 8,955 |
| VNRA regulatory | 3404 | DKK 10,378 |
| MRP-CMS | VNRA administrative | 3405 | DKK 2,026 |
| VNRA regulatory | 3406 | DKK 4,170 |
| VRA Quality | National | VRA Reduced | 3407 | DKK 13,960 |
| VRA Standard Simple | 3408 | DKK 33,122 |
| VRA Standard Complex | 3409 | DKK 52,285 |
| MRP-RMS | VRA Reduced | 3410 | DKK 21,771 |
| VRA Standard Simple | 3411 | DKK 40,512 |
| VRA Standard Complex | 3412 | DKK 59,253 |
| MRP-CMS | VRA Reduced | 3413 | DKK 2,026  |
| VRA Standard Simple | 3414 | DKK 2,026  |
| VRA Standard Complex | 3415 | DKK 2,026  |
| VRA regulatory | National | VRA Reduced | 3416 | DKK 10,846 |
| VRA Standard | 3417 | DKK 27,016 |
| MRP-RMS | VRA Reduced | 3418 | DKK 11,802 |
| VRA Standard | 3419 | DKK 20,879 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  | MRP-CMS | VRA Reduced | 3420 | DKK 6,315 |
| VRA Standard | 3421 | DKK 6,315  |
| VRA Extended | National | VRA Extended | 3422 | DKK 63,130 |
| MRP-RMS | VRA Extended | 3423 | DKK 71,054 |
| MRP-CMS | VRA Extended | 3424 | DKK 8,340  |
| Grouping and worksharing | VRA Quality | National | VRA Reduced | 3425 | DKK 29,069 |
| VRA Standard Simple | 3426 | DKK 43,827 |
| VRA Standard Complex | 3427 | DKK 58,584 |
| MRP-RMS | VRA Reduced | 3428 | DKK 37,008 |
| VRA Standard Simple | 3429 | DKK 52,872 |
| VRA Standard Complex | 3430 | DKK 68,737 |
| MRP, reference authority in case of worksharing | VRA Reduced | 3431 | DKK 55,076 |
| VRA Standard Simple | 3432 | DKK 81,430 |
| VRA Standard Complex | 3433 | DKK 107,785 |
| MRP-CMS | VRA Reduced grouping | 3434 | DKK 3,547  |
| VRA Reduced worksharing | 3435 | DKK 3,547  |
| VRA Standard Simple grouping | 3436 | DKK 5,362 |
| VRA Standard Simple worksharing | 3437 | DKK 5,362 |
| VRA Standard Complex grouping | 3438 | DKK 7,179 |
| VRA Standard Complex worksharing | 3439 | DKK 7,179 |
| VRA regulatory | National | VRA Reduced | 3440 | DKK 18,510 |
| VRA Standard | 3441 | DKK 33,285 |
| MRP-RMS | VRA Reduced | 3442 | DKK 18,573 |
| VRA Standard | 3443 | DKK 32,195 |
| MRP, reference authority in case of worksharing | VRA Reduced | 3444 | DKK 43,421 |
| VRA Standard | 3445 | DKK 51,970kr. |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  | MRP-CMS | VRA Reduced grouping | 3446 | DKK 9,955 |
| VRA Standard grouping | 3447 | DKK 9,955 |
| VRA Reduced worksharing | 3448 | DKK 9,955 |
| VRA Standard worksharing | 3449 | DKK 9,955 |
| VRA Extended | National | VRA Extended | 3450 | DKK 77,096 |
| VRA Extended Mix | 3451 | DKK 91,870 |
| MRP-RMS | VRA Extended | 3452 | DKK 87,309 |
| VRA Extended Mix | 3453 | DKK 100,931 |
| MRP, reference authority in case of worksharing | VRA Extended | 3454 | DKK 151,206 |
| VRA Extended Mix | 3455 | DKK 159,756 |
| MRP-CMS | VRA Extended grouping | 3456 | DKK 17,134 |
| VRA Extended Mix grouping | 3457 | DKK 17,134 |
| VRA Extended worksharing | 3458 | DKK 17,134 |
| VRA Extended Mix worksharing | 3459 | DKK 17,134 |

Fees for application for authorisation or registration of companies as well as annual fee for authorised or

registered companies

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Company** | **Explanation** | **Danish Medicines Agency’s item number** | **Application****fee** | **Annual fee** |
| **Manufacturing and import of medicinal products and intermediate products** | Authorisation to manufacture and import medicinal products, cf. section 39(1) of the Danish Medicines Act, and intermediate products, cf. section 39(2) of the Danish Medicines Act. If the company employs more than 500 employees at one location at the time of applying (with application fee) or on 1 January (with annual fee), an additional fee is charged, see item number 5021/5022. | 5001/5002 | DKK 72,250 | DKK 72,219 |
| **Wholesale distribution of medicinal products** |  | 5003/5004 | DKK 12,701 |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Authorisation for wholesale distribution of medicinal products, cf. section 39(1) of the Danish Medicines Act. |  |  | DKK 12,740 |
| **Retail sale of OTC medicines** | Authorisation for retail sale of medicinal products, cf. section 39(1) of the Danish Medicines Act. See below about fees for retail sale of medical gases and smoking cessation products. | 5005/5006 | DKK 941 | DKK 941 |
| **Retail sale of medical gases** | Authorisation for retail sale of medical gases, cf. section 39(1) of the Danish Medicines Act. | 5007/5008 | DKK 1,304 | DKK 1,304 |
| **Retail sale of smoking cessation products** | Authorisation for retail sale of smoking cessation products, cf. section 39(1) of the Danish Medicines Act. | 5009 | Calculated individually based on the time spent by the DKMA (per half hour commenced) and hourly rate: DKK 1,018 |  |
| **Retail sale of medicinal products for production animals** | Authorisation for retail sale of medicinal products for production animals, cf. section 39 of the Danish Medicines Act | 5010 | DKK 54,104 | Administration fee amounts to 0.065 per cent of the distributor’s total sale of medicinal products for production animals |
| **Brokering of medicinal products** | Registration of company engaging in brokering of medicinal products, cf. section 41b(1) of the Danish Medicines Act | 5011/5012 | DKK 17,360 | DKK 17,360 |
| **API manufacturing** | Registration of company manufacturing active substances | 5013/5014 | DKK 72,250 |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | intended for use in the manufacturing of medicinal products, cf. section 50a(1) of the Danish Medicines Act. If the company employs more than 500 employees at one location at the time of applying (with application fee) or on 1 January (with annual fee), an additional fee is charged, see item number 5021/5022. |  |  | DKK 72,219 |
| **API import and distribution** | Registration of company importing and distributing active substances intended for use in the manufacturing of medicinal products, cf. section 50a(1) of the Danish Medicines Act. | 5015/5016 | DKK 12,701 | DKK 12,740 |
| **Toxicological and pharmacological trials (GLP)** | Authorisation to conduct toxicological and pharmacological (non-clinical) trials, cf. section 85(1) of the Danish Medicines Act If the company employs more than 500 employees at one location at the time of applying (with application fee) or on 1 January (with annual fee), an additional fee is charged, see item number 5021/5022. | 5017/5018 | DKK 72,250 | DKK 72,219 |
| **API inspection outside the EU** | Inspection of company with API outside the EU, cf. section 10. | 5019 | DKK 162,568 | DKK 162,568 |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Inspection of the manufacturing of products or data, for which import authorities require a GMP or GLP statement** | Inspection of company in Denmark not covered by an authorisation or registration, cf. section 10. | 5020 | Calculated individually and charged by hourly rate based on time consumption (per commenced hour) plus any other direct costs paid by the Danish Medicines Agency as part of the inspection.Hourly rate:DKK 1,242 |  |
| **Additional fee for locations with more than 500 employees** | The fee is charged in the case of manufacture and import of medicinal products and intermediates, API manufacturing and toxicological and pharmacological trials (GLP) if the company employs more than 500 employees at one location at the time of applying (with application fee) or on 1 January (with annual fee) | 5021/5022 | DKK 168,759 | DKK 168,759 |
| **Distribution and dispensing of medical chests and motion sickness tablets for lifeboats and life rafts** | Authorisation to distribute and dispense medical chests with medicinal products for lifeboats and life rafts, cf. section 39(1) of the Danish Medicines Act. | 5032/5033 | DKK 28,954 | DKK 28,954 |

 Fees for notification about prices etc.

|  |  |  |  |
| --- | --- | --- | --- |
| **Company** | **Explanation** | **Danish Medicines Agency’s item number** | **Fee** |
| **Pharmacy** | Notification of consumer prices, etc. of pharmacy-only medicinal products to the pharmacies | 6001 | DKK 2,850 |
| **Subscribers** | Subscription for Medicine Prices for companies | 6002 | DKK 3,561,25incl. VAT |

 Special fees for medicinal products manufactured at a company outside the EU/EEA area

|  |  |  |  |
| --- | --- | --- | --- |
| **Additional fee** | **Description** | **Danish Medicines Agency’s item number** | **Fee** |
| **Additional fee for application for marketing authorisation, cf. section 16(1)** | Additional fee for application for marketing authorisation if the medicinal product is manufactured outside the EU/EEA area, and the Danish Medicines Agency is obliged to inspect the company under current EU legislation | 3049 | DKK 1,026 |
| **Additional fee for application for variation of marketing authorisation, cf. section 16(2)** | Additional fee for application for variation of marketing authorisation if the manufacturing site of the medicinal product is changed to a company outside the EU/EEA area, and the Danish Medicines Agency is obliged to inspect the company under current EU legislation. | 3140 | DKK 1,026 |
| **Additional fee to the annual fee for medicinal products, cf. section 16(3)** | Additional fee to the annual fee for medicinal products manufactured outside the EU/EEA area if the Danish Medicines Agency is obliged to inspect the company under current EU legislation. | 3048 | DKK 1,164 |