# TARIFFS

**for assessment of documentation in view of marketing authorisation/marketing authorisation renewal/marketing authorisation variation of medicinal products for human use and development of marketing authorisation related activities**

**in accordance with Law no. 95/2006 as amended, Order of the Minister of Health no. 716/2009 published in the Official Gazette of Romania, Part I, no. 422 of 19 June 2009 and Order No.868 of 07.09.2012 published in the Official Gazette of Romania, Part I, no. 667 of 24 September 2012**

| Nr. crt. | Performance | Tariff – euro – |
|---|---|---|
| | **Tax provided for marketing authorisation application according to Article 854 of Law no. 95/2006 on healthcare reform.** | 1,000 |

| Nr. crt. | Performance | Tariff – euro – |
|---|---|---|
| **A.** | **Assessment of documentation in view of marketing authorisation/marketing authorisation renewal through national procedure** | |
| 1. | Marketing authorisation of medicinal products submitted – full dossier, according to Article 702(4), of Law No. 95/2006 on healthcare reform, with further amendments and supplementations, or Article 8 (3) 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 through national procedure | 9,500 |
| 1.a) | Marketing authorisation of medicinal products submitted – full dossier according to Article 702(4), of Law No. 95/2006, with further amendments and supplementations, or Article 8 (3) of Directive 2001/83 EC – different pharmaceutical form submitted at the same time with the initial application through national procedure | 4,750 |
| 1.b) | Marketing authorisation of medicinal products submitted – full dossier, according to Article 702(4), of Law No. 95/2006 with further amendments and supplementations, or Article 8 (3) of Directive 2001/83 EC – the second and following strengths submitted at the same time with initial application through national procedure | 2,830 |
| 2. | Marketing authorisation of generic medicinal products submitted according to Article 704(1) and (2) of Law No. 95/2006, with further amendments and | 5,700 |

| Nr. crt. | Performance | Tariff – euro – |
|---|---|---|
| | supplementations, or Article 10 (1) of Directive 2001/83 EC through national procedure | |
| 2.a) | Marketing authorisation of generic medicinal products submitted according to Article 704(1) and (2) of Law No. 95/2006, with further amendments and supplementations, or Article 10 (1) of Directive 2001/83 EC – different pharmaceutical form submitted at the same time with the initial application through national procedure | 2,900 |
| 2.b) | Marketing authorisation of generic medicinal products submitted according to Article 704(1) and (2) of Law No. 95/2006, with further amendments and supplementations, or Article 10 (1) of Directive 2001/83 EC – the second and following strengths submitted at the same time with the initial application through national procedure | 1,710 |
| 3. | Marketing authorisation of medicinal products submitted – "hybrid" (mixed) application according to Article 704(3) of Law No. 95/2006, with further amendments and supplementations, or Article 10 (3) of Directive 2001/83 EC through national procedure | 6,650 |
| 3.a) | Marketing authorisation of medicinal products submitted as "hybrid" (mixed) application according to Article 704(3) of Law No. 95/2006, with further amendments and supplementations, or Article 10 (3) of Directive 2001/83 EC – different pharmaceutical form submitted at the same time with the initial application through national procedure | 3,325 |
| 3.b) | Marketing authorisation of medicinal products submitted as "hybrid" (mixed) application according to Article 704(3) of Law No. 95/2006, with further amendments and supplementations, or Article 10 (3) of Directive 2001/83 EC, the second and following strengths submitted at the same time with the initial application through national procedure | 2,000 |
| 4. | Marketing authorisation of biosimilar medicinal products, submitted according to Article 704(4) of Law No. 95/2006, with further amendments and supplementations, or Article 10 (4) of Directive 2001/83 EC through national procedure | 6,650 |
| 4.a) | Marketing authorisation of biosimilar medicinal products submitted according to Article 704(4) of Law No. 95/2006, with further amendments and supplementations, or Article 10 (4) of Directive 2001/83 EC – different pharmaceutical form submitted at the same time with the initial application through national procedure | 3,325 |
| 4.b) | Marketing authorisation of biosimilar medicinal products, submitted according to Article 704(4) of Law No. 95/2006, with further amendments and supplementations, or Article 10 (4) of Directive 2001/83 EC – the second and following strengths submitted at the same time with the initial application through national procedure | 2,000 |
| 5. | Marketing authorisation of well–established use medicinal products, submitted according to Article 705 of Law No. 95/2006, with further | 6,650 |

| Nr. crt. | Performance | Tariff – euro – |
|---|---|---|
| | amendments and supplementations, or Article 10 (a) of Directive 2001/83 EC ("bibliographic" application) through national procedure | |
| 5.a) | Marketing authorisation of well–established use medicinal products, submitted according to Article 705 of Law No. 95/2006, with further amendments and supplementations, or Article 10 (a) of Directive 2001/83 EC ("bibliographic" application) – different pharmaceutical form submitted at the same time with the initial application through national procedure | 3,325 |
| 5.b) | Marketing authorisation of well–established use medicinal products submitted according to Article 705 of Law No. 95/2006, with further amendments and supplementations, or Article 10 (a) of Directive 2001/83 EC ("bibliographic" application) – the second and following strengths submitted at the same time with the initial application through national procedure | 2,000 |
| 6. | Marketing authorisation of fixed combination medicinal products, submitted according to Article 706 of Law No. 95/2006, with further amendments and supplementations, or Article 10 (b) of Directive 2001/83 EC through national procedure | 8,035 |
| 6.a) | Marketing authorisation of fixed combination medicinal products, submitted according to Article 706 of Law No. 95/2006, with further amendments and supplementations, or Article 10 (b) of Directive 2001/83 EC – different pharmaceutical form submitted at the same time with the initial application through national procedure | 4,005 |
| 6.b) | Marketing authorisation of fixed combination medicinal products, submitted according to Article 706 of Law No. 95/2006, with further amendments and supplementations, or Article 10 (b) of Directive 2001/83 EC – the second and following strengths submitted at the same time with the initial application through national procedure | 2,450 |
| 7. | Marketing authorisation of informed consent medicinal products submitted according to Article 707 of Law No. 95/2006, with further amendments and supplementations, or Article 10 (c) of Directive 2001/83 EC through national procedure | 2,850 |
| 7.a) | Marketing authorisation of informed consent medicinal products submitted according to Article 707 of Law No. 95/2006, with further amendments and supplementations, or Article 10 (c) of Directive 2001/83 EC – different pharmaceutical form submitted at the same time with the initial application through national procedure | 1,425 |
| 7.b) | Marketing authorisation of informed consent medicinal products submitted according to Article 707 of Law No. 95/2006, with further amendments and supplementations, or Article 10 (c) of Directive 2001/83 EC – the second and following strengths submitted at the same time with the initial application through national procedure | 900 |
| 8. | Marketing authorisation of homeopathic medicinal products, submitted according to Article 710 of Law No. 95/2006, with further amendments and | 1,920 |

| Nr. crt. | Performance | Tariff – euro – |
|---|---|---|
| | supplementations (Marketing authorisation through simplified procedure) through national procedure | |
| 9. | Marketing authorisation of traditional herbal medicinal products granted according to Article 714 of Law No. 95/2006, with further amendments and supplementations (Marketing authorisation through simplified procedure) through national procedure | 1,920 |
| 10. | Marketing authorisation of medicinal products submitted as line extensions of an already authorised medicinal product through national procedure | 4,100 |
| 11. | Marketing authorisation renewal according to Article 730(2) of Law No. 95/2006, with further amendments and supplementations, or Article 24 (2) of Directive 2001/83 EC through national procedure | 2,400 |
| 12. | Marketing authorisation renewal of homeopathic medicinal products, submitted according to Article 710 of Law No. 95/2006, with further amendments and supplementations, (marketing authorisation through simplified procedure) through national procedure | 970 |
| 13. | Marketing authorisation renewal of traditional herbal medicinal products granted according to Article 714 of Law No. 95/2006, with further amendments and supplementations (Marketing authorisation through simplified procedure) through national procedure | 970 |
| **B.** | **Assessment of documentation in view of marketing authorisation/marketing authorisation renewal through European procedures** | |
| 14. | Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State – generic medicinal products [Article 10 (1) of Directive 2001/83 EC or Article 704(1) and (2) of Law No. 95/2006, with further amendments and supplementations] | 8,050 |
| 14.a) | Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State – generic medicinal products – different pharmaceutical form submitted at the same time with the initial application [Article 10 (1) of Directive 2001/83 EC or Article 704(1) and (2) of Law No. 95/2006, with further amendments and supplementations] | 4,830 |
| 14.b) | Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State – generic medicinal products – the second and following strengths submitted at the same time with the initial application [Article 10 (1) of Directive 2001/83 EC or Article 704(1) and (2) of Law No. 95/2006, with further amendments and supplementations] | 2,420 |
| 15. | Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State – "hybrid" (mixed) application [Article 10 (3) of Directive 2001/83 EC | 9,200 |

| Nr. crt. | Performance | Tariff – euro – |
|---|---|---|
| | or Article 704(3) of Law No. 95/2006, with further amendments and supplementations] | |
| 15.a) | Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State – "hybrid" (mixed) application – different pharmaceutical form submitted at the same time with the initial application [Article 10 (3) of Directive 2001/83 EC or Article 704(3) of Law No. 95/2006, with further amendments and supplementations] | 5,520 |
| 15.b) | Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State – "hybrid" (mixed) application – the second and following strengths submitted at the same time with the initial application [Article 10 (3) of Directive 2001/83 EC or Article 704(3) of Law No. 95/2006, with further amendments and supplementations] | 2,760 |
| 16. | Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State – "biosimilar medicinal product" [Article 10 (4) of Directive 2001/83 EC or Article 704(4) of Law No. 95/2006, with further amendments and supplementations] | 9,200 |
| 16.a) | Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State – "biosimilar medicinal product" – different pharmaceutical form submitted at the same time with the initial application [Article 10 (4) of Directive 2001/83 EC or Article 704(4) of Law No. 95/2006, with further amendments and supplementations] | 5,520 |
| 16.b) | Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State – "biosimilar medicinal product" – the second and following strengths submitted at the same time with the initial application [Article 10 (4) of Directive 2001/83 EC or Article 704(4) of Law No. 95/2006, with further amendments and supplementations] | 2,760 |
| 17. | Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State – "bibliographic" application [Article 10 (a) of Directive 2001/83 EC or Article 705 of Law No. 95/2006, with further amendments and supplementations] | 9,200 |
| 17.a) | Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State – "bibliographic" application – different pharmaceutical form submitted at the same time with the initial application [Article 10 (a) of Directive 2001/83 EC or Article 705 of Law No. 95/2006, with further amendments and supplementations] | 5,520 |

| Nr. crt. | Performance | Tariff – euro – |
|---|---|---|
| 17.b) | Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State – "bibliographic" application – the second and following strengths submitted at the same time with the initial application [Article 10 (a) of Directive 2001/83 EC or Article 705 of Law No. 95/2006, with further amendments and supplementations] | 2,760 |
| 18. | Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State – fixed combination [Article 10 (b) of Directive 2001/83 EC or Article 706 of Law No. 95/2006, with further amendments and supplementations] | 9,780 |
| 18.a) | Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State – fixed combination – different pharmaceutical form submitted at the same time with the initial application [Article 10 (b) of Directive 2001/83 EC or Article 706 of Law No. 95/2006, with further amendments and supplementations] | 5,870 |
| 18.b) | Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State – fixed combination – the second and following strengths submitted at the same time with the initial application [Article 10 (b) of Directive 2001/83 EC or Article 706 of Law No. 95/2006, with further amendments and supplementations] | 2,930 |
| 19. | Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State – "informed consent" [Article 10 (c) of Directive 2001/83 EC or Article 707 of Law No. 95/2006, with further amendments and supplementations] | 6,900 |
| 19.a) | Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State – informed consent – different pharmaceutical form submitted at the same time with the initial application [Article 10 (c) of Directive 2001/83 EC or Article 707 of Law No. 95/2006, with further amendments and supplementations] | 4,140 |
| 19.b) | Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State – "informed consent" – the second and following strengths submitted at the same time with the initial application [Article 10 (c) of Directive 2001/83 EC or Article 707 of Law No. 95/2006, with further amendments and supplementations] | 2,070 |
| 20. | Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State – full dossier [Article 8 (3) of Directive 2001/83 EC or Article 702(4) of Law No. 95/2006, with further amendments and supplementations] | 7,500 |

| Nr. crt. | Performance | Tariff – euro – |
|---|---|---|
| 20.a) | Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State – full dossier – different pharmaceutical form submitted at the same time with the initial application [Article 8 (3) of Directive 2001/83 EC or Article 702(4) of Law No. 95/2006, with further amendments and supplementations] | 4,500 |
| 20.b) | Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State – full dossier – the second and following strengths submitted at the same time with the initial application [Article 8 (3) of Directive 2001/83 EC or Article 702(4) of Law No. 95/2006, with further amendments and supplementations] | 2,250 |
| 21. | Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State – generic medicinal products [Article 10 (1) of Directive 2001/83 EC or Article 704(1) and (2) of Law No. 95/2006, with further amendments and supplementations] | 5,200 |
| 21.a) | Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State – generic medicinal products – different pharmaceutical form submitted at the same time with the initial application [Article 10 (1) of Directive 2001/83 EC or Article 704(1) and (2) of Law No. 95/2006, with further amendments and supplementations] | 3,120 |
| 21.b) | Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State – generic medicinal products – the second and following strengths submitted at the same time with the initial application [Article 10 (1) of Directive 2001/83 EC or Article 704(1) and (2) of Law No. 95/2006, with further amendments and supplementations] | 1,560 |
| 22. | Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State – “hybrid” (mixed) application [Article 10 (3) of Directive 2001/83 EC or Article 704(3) of Law No. 95/2006, with further amendments and supplementations] | 6,000 |
| 22.a) | Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State – “hybrid” (mixed) application – different pharmaceutical form submitted at the same time with the initial application [Article 10 (3) of Directive 2001/83 EC or Article 704(3) of Law No. 95/2006, with further amendments and supplementations] | 3,600 |
| 22.b) | Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member | 1,800 |

| Nr. crt. | Performance | Tariff – euro – |
|---|---|---|
| | State – "hybrid" (mixed) application – the second and following strengths submitted at the same time with the initial application [Article 10 (3) of Directive 2001/83 EC or Article 704(3) of Law No. 95/2006, with further amendments and supplementations] | |
| 23. | Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State – "biosimilar medicinal product" [Article 10 (4) of Directive 2001/83 EC or Article 704(4) of Law No. 95/2006, with further amendments and supplementations] | 6,000 |
| 23.a) | Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State – biosimilar medicinal products– different pharmaceutical form submitted at the same time with the initial application [Article 10 (4) of Directive 2001/83 EC or Article 704(4) of Law No. 95/2006, with further amendments and supplementations] | 3,600 |
| 23.b) | Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State – "biosimilar medicinal product"– the second and following strengths submitted at the same time with the initial application [Article 10 (4) of Directive 2001/83 EC or Article 704(4) of Law No. 95/2006, with further amendments and supplementations] | 1,800 |
| 24. | Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State – "bibliographic" application [Article 10 (a) of Directive 2001/83 EC or Article 705 of Law No. 95/2006, with further amendments and supplementations] | 6,000 |
| 24.a) | Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State – "bibliographic" application – different pharmaceutical form submitted at the same time with the initial application [Article 10 (a) of Directive 2001/83 EC or Article 705 of Law No. 95/2006, with further amendments and supplementations] | 3,600 |
| 24.b) | Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State – "bibliographic" application – the second and following strengths submitted at the same time with the initial application [Article 10 (a) of Directive 2001/83 EC or Article 705 of Law No. 95/2006, with further amendments and supplementations] | 1,800 |
| 25. | Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State – fixed combination [Article 10 (b) of Directive 2001/83 EC or Article 706 of Law No. 95/2006, with further amendments and supplementations] | 6,400 |

| Nr. crt. | Performance | Tariff – euro – |
|---|---|---|
| 25.a) | Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State – fixed combination – different pharmaceutical form submitted at the same time with the initial application [Article 10 (b) of Directive 2001/83 EC or Article 706 of Law No. 95/2006, with further amendments and supplementations] | 3,840 |
| 25.b) | Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State – fixed combination – the second and following strengths submitted at the same time with the initial application [Article 10 (b) of Directive 2001/83 EC or Article 706 of Law No. 95/2006, with further amendments and supplementations] | 1,920 |
| 26. | Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State – "informed consent" [Article 10 (c) of Directive 2001/83 EC or Article 707 of Law No. 95/2006, with further amendments and supplementations] | 3,750 |
| 26.a) | Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State – "informed consent" – different pharmaceutical form submitted at the same time with the initial application [Article 10 (c) of Directive 2001/83 EC or Article 707 of Law No. 95/2006, with further amendments and supplementations] | 2,250 |
| 26.b) | Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State – "informed consent" – the second and following strengths submitted at the same time with the initial application [Article 10 (c) of Directive 2001/83 EC or Article 707 of Law No. 95/2006, with further amendments and supplementations] | 1,130 |
| 27. | Marketing authorisation renewal of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State | 2,100 |
| 27.a) | Renewal of medicinal product marketing authorisation through the mutual recognition and the decentralised procedure with Romania as Reference Member State | 4,305 |
| **C.** | **Approval of clinical trials and advertising material** | |
| 28. | Approval of clinical trials for investigational medicinal products not authorised worldwide (new substances). Phases I–III | 1,250 |
| 29. | Approval of clinical trials for investigational medicinal products not authorised for marketing in Romania, authorised in other countries or authorised for marketing (known substances) but not used according to Summary of Product Characteristics (SPC) in force in the respective trial (regarding indications, dose, administration route, treatment method, target | 1,000 |

| Nr. crt. | Performance | Tariff – euro – |
|---|---|---|
| | group). Phases I – III | |
| 30. | Approval of clinical trials for medicinal products authorised in Romania, used according to SPC in force. Phase IV | 410 |
| 31. | Approval of bioequivalence studies | 600 |
| 32. | Approval of changes to protocol/investigational medicinal product (according to Decision of the National Medicines Agency Scientific Council no. 49/2006 – Annex 5) | 200 |
| 33. | Approval of advertising material for "Over the Counter" medicinal products (OTCs ) | 550 |
| 34. | Approval of educational material for medicinal products for human use | 350 |
| **D.** | **Approval of variations** | |
| 35. | Approval of Type IA variations and Type IA variations describing the group for medicinal products authorised through national procedure | 300 |
| 36. | Approval of Type IB variations and Type IB variations describing the group for medicinal products authorised through national procedure | 500 |
| 37. | Approval of Type II variations and Type II variations describing the group for medicinal products authorised through national procedure | 1,600 |
| 38. | Approval of Type IA variations included into the group for medicinal products authorised through national procedure | 200 |
| 39. | Approval of Type IB variations included into the group for medicinal products authorised through national procedure | 340 |
| 40. | Approval of Type II variations included into the group for medicinal products authorised through national procedure | 1,070 |
| 41. | Approval of Type IA variations for medicinal products authorised through mutual recognition and decentralised procedures with Romania as Reference Member State | 460 |
| 42. | Approval of Type IB variations for medicinal products authorised through mutual recognition and decentralised procedures with Romania as Reference Member State | 760 |
| 43. | Approval of Type II variations for medicinal products authorised through mutual recognition and decentralised procedures with Romania as Reference Member State | 2,400 |
| 44. | Approval of Type IA variations for medicinal products authorised through mutual recognition and decentralised procedures with Romania as Concerned Member State | 300 |
| 45. | Approval of Type IB variations for medicinal products authorised through mutual recognition and decentralised procedures with Romania as Concerned Member State | 500 |
| 46. | Approval of Type II variations for medicinal products authorised through mutual recognition and decentralised procedures with Romania as Concerned Member State | 1,600 |
| 47. | Approval of Type IA variations included into the group, other than the | 375 |

| Nr. crt. | Performance | Tariff – euro – |
|---|---|---|
| | variation describing the group, for medicinal products authorised through mutual recognition and decentralised procedures with Romania as Reference Member State | |
| 47.a) | Approval of Type IB variations included into the group, other than the variation describing the group, for medicinal products authorised through mutual recognition and decentralised procedures with Romania as Reference Member State | 750 |
| 47.b) | Approval of Type II variations included into the group, other than the variation describing the group, for medicinal products authorised through mutual recognition and decentralised procedures with Romania as Reference Member State | 2,400 |
| 48. | Approval of Type IA variations included into the group, other than the variation describing the group, for medicinal products authorised through mutual recognition and decentralised procedures with Romania as Concerned Member State | 165 |
| 48.a) | Approval of Type IB variations included into the group, other than the variation describing the group, for medicinal products authorised through mutual recognition and decentralised procedures with Romania as Concerned Member State | 225 |
| 48.b) | Approval of Type II variations included into the group, other than the variation describing the group, for medicinal products authorised through mutual recognition and decentralised procedures with Romania as Concerned Member State | 825 |
| **E.** | **Other marketing authorisation related activities** | |
| 49. | Approval of marketing authorisation transfer | 400 |
| 50. | Approval of changes in primary and secondary packaging design and labelling, regarding changes to Leaflet and SPC, other than resulting from Type IA, IB and Type II variations | 250 |
| 51. | Grant of WHO – format medicinal product certificate | 230 |
| 52. | Marketing authorisation maintenance fee | 230 |
| 53. | Grant of parallel import authorisation | 585 |
| 54. | Approval of variations to parallel import authorisations | 250 |

NOTICE

1. The fee should be paid for each variation of each marketing authorization.
2. In case of grouped variations different fees for the main variation in the group (defining the group) and the rest of variations included in the group are applicable.
3. The total fee to be paid in case of grouping has to be calculated for each marketing authorisation, by summation of the fee for the variation that defines (describe) the group and the fee for variation

included in the group applied to each variation in the group, other than the variation defining the group.

4. The fee for the variation defining (describing) the group is the fee for the variation to the marketing authorisation.