**ZAHTJEV ZA PRIJENOS ODOBRENJA ZA STAVLJANJE LIJEKA U PROMET**

***APPLICATION FOR TRANSFER OF MARKETING AUTHORISATION***

*NAPOMENA: za nacionalno odobrene lijekove i lijekove odobrene u istom DCP/MRP postupku moguće je jednim obrascem podnijeti više zahtjeva za više lijekova za koje se traži isti datum prijenosa odobrenja
NOTE: for nationally authorised products and for the products authorised within the same DCP/MRP procedure a single application form may cover several applications for medicinal products for which the same date of the transfer is being requested*

1. **Podaci o lijeku:**

**Medicinal product details:**

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| Naziv lijeka:Name of the medicinal product: | Kliknite za upis | Click here to enter text. |
| Broj odobrenja (ili klasa rješenja ako broj odobrenja nije dodijeljen):Marketing authorisation number (or classification number of the authorisation in case the marketing authorisation number is not yet assigned): | Kliknite za upis | Click here to enter text. |

1. **Podaci o dosadašnjem nositelju odobrenja za stavljanje lijeka u promet:**

**Current marketing authorisation holder details:**

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| Naziv dosadašnjeg nositelja odobrenja:Name of the current marketing authorisation holder: | Kliknite za upis | Click here to enter text. |
| Adresa (ulica i kućni broj, grad, država):Full address (street name and house number, city, country): | Kliknite za upis | Click here to enter text. |

1. **Podaci o budućem nositelju odobrenja za stavljanje lijeka u promet:**

**Future marketing authorisation holder details:**

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| Naziv budućeg nositelja odobrenja:Name of the future marketing authorisation holder: | Kliknite za upis | Click here to enter text. |
| Adresa (ulica i kućni broj, grad, država):Full address (street name and house number, city, country): | Kliknite za upis | Click here to enter text. |

1. **Napomena:**

**Note:**

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| Kliknite za upis | Click here to enter text. |

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| 1. **Priložena dokumentacija:**

**Attached documents:** |
|[ ]  **izjava dosadašnjeg nositelja odobrenja da je suglasan s prijenosom odobrenja za stavljanje lijeka u promet na drugu fizičku ili pravnu osobu, kao i prijenosom svih prava i obveza nositelja odobrenja, cjelokupne dokumentacije o lijeku na temelju koje je odobrenje dano zajedno sa svom dokumentacijom odobrenom nakon davanja odobrenja u postupcima izmjene i obnove, kao i prijenosom svih zahtjeva koji su u postupku rješavanja pri Agenciji podneseni od strane dosadašnjeg nositelja odobrenja (izjava mora sadržavati naziv i broj odobrenja lijeka te naziv i adresu fizičke ili pravne osobe na koju se prenosi odobrenje)****statement given by the current marketing authorisation holder consenting with the transfer of the marketing authorisation to another natural or legal person, as well as with the transfer of all rights and obligations of the marketing authorisation holder, complete medicinal product dossier based on which the authorisation was granted including all post-authorisation documentation approved via variation and renewal procedures, as well as with the transfer of all pending applications within the Agency, submitted by the current marketing authorisation holder (statement must include the name and the marketing authorisation number of the medicinal product, as well as the name and the address of the future natural or legal person to whom the marketing authorisation for the medicinal product is being transferred)** |
|[ ]  **izjava fizičke ili pravne osobe na koju se prenosi odobrenje za stavljanje lijeka u promet da prihvaća prijenos odobrenja, sva prava i obveze dosadašnjeg nositelja odobrenja za lijek, cjelokupnu dokumentaciju o lijeku na temelju koje je odobrenje dano zajedno sa svom dokumentacijom odobrenom nakon davanja odobrenja u postupcima izmjene i obnove, kao i sve zahtjeve koji su u postupku rješavanja pri Agenciji podneseni od strane dosadašnjeg nositelja odobrenja (izjava mora sadržavati naziv i broj odobrenja lijeka, naziv i adresu dosadašnjeg nositelja odobrenja te datum preuzimanja prava i obveza fizičke ili pravne osobe na koju se prenosi odobrenje)****statement given by the natural or legal person to whom the marketing authorisation for the medicinal product is being transferred, accepting the transfer of the marketing authorisation, all the rights and obligations of the current marketing authorisation holder, the complete medicinal product dossier based on which the authorisation was granted including all post-authorisation documentation approved via variation and renewal procedures, as well as all pending applications within the Agency submitted by the current marketing authorisation holder (statement must include the name and the marketing authorisation number of the medicinal product, the name and the address of the current marketing authorisation holder as well as the date from which the rights and the responsibilities will be transferred to another natural or legal person)** |
|[ ]  **dokaz da se sjedište fizičke ili pravne osobe na koju se prenosi odobrenje za stavljanje lijeka u promet nalazi na području Europske unije**proof that the seat of the natural or legal person to whom the marketing authorisation is being transferred is in the territory of the European Union |
|[ ]  **ovlaštenje fizičke ili pravne osobe na koju se prenosi odobrenje kojim ovlašćuje osobu za podnošenje zahtjeva i komunikaciju s Agencijom (za regulatorne postupke nakon prijenosa)****authorisation given by the natural or legal person** to whom the marketing authorisation is being transferred **authorising the person to submit the application and communicate with the Agency (for the regulatory procedures following the transfer of the marketing authorisation)** |
|[ ]  **izjava fizičke ili pravne osobe na koju se prenosi odobrenje koja nema sjedište, odnosno prebivalište u Republici Hrvatskoj kojom imenuje svog predstavnika sa sjedištem u Republici Hrvatskoj, uključujući podatke propisane člankom 79. stavkom 2. točkom 2. Pravilnika o davanju odobrenja za stavljanje lijeka u promet (»Narodne novine«, br. 83/13., 28/20. i** 32/21.**), ako je primjenjivo****statement given by the natural or legal person** to whom the marketing authorisation is being transferred **not seated in the Republic of Croatia appointing the local representative seated in the Republic of Croatia, including all the information stipulated by Article 79 paragraph 2 point 2 of the** Ordinance on Granting Marketing Authorisations for Medicinal Products (Official Gazette No. 83/13, 28/20 and 32/21)**, if applicable** |
|[ ]  **dokaz da fizička ili pravna osoba na koju se prenosi odobrenje ima osobu odgovornu za farmakovigilanciju s prebivalištem u Republici Hrvatskoj odobrenu od Agencije, odnosno dokaz o predanom zahtjevu Agenciji za odobrenje osobe odgovorne za farmakovigilanciju s prebivalištem u Republici Hrvatskoj****proof that the natural or legal person** to whom the marketing authorisation is being transferred **has the person responsible for pharmacovigilance residing in the Republic of Croatia approved by the Agency, or proof of the submitted request to the Agency for approval of the person responsible for pharmacovigilance residing in the Republic of Croatia** |
|[ ]  **prijedlog sažetka opisa svojstava lijeka, upute o lijeku i označivanja lijeka s upisanim podacima o fizičkoj ili pravnoj osobi na koju se prenosi odobrenje te o predstavniku nositelja odobrenja, ako je primjenjivo****proposal of the Summary of Product Characteristics, Package Leaflet and labelling with the data on the natural or legal person to whom the marketing authorisation is being transferred as well as the data on the local representative, if applicable** |
|[ ]  **izjava fizičke ili pravne osobe na koju se prenosi odobrenje za lijek odobren nacionalnim postupkom kojom potvrđuje da raspolaže potrebnim sredstvima za ispunjavanje dužnosti i odgovornosti prema odredbama Zakona o lijekovima, odnosno Glave IX Direktive 2001/83/EZ ili sažetak glavnog spisa o farmakovigilancijskom sustavu (sPSMF) koji sadrži traženu izjavu****(Izjavu je za nacionalno odobrene lijekove potrebno dostaviti u slučaju da prijenos uvjetuje promjenu farmakovigilancijskog sustava. Za lijekove odobrene MRP/DCP postupkom potrebno je slijediti dokument objavljen na stranicama CMDh „*Q&A - List for the submission of variations according to Commission Regulation (EC) 1234/2008*“)****statement given by the natural or legal person** to whom the marketing authorisation is being transferred for the nationally authorised medicinal product, confirming that marketing authorisation holder has the necessary means to fulfil the tasks and responsibilities listed in the Medicinal Products Act and in Title IX of the Directive 2001/83/EC, or alternatively the Summary of the Pharmacovigilance System Master File (sPSMF) which includes this statement**(For the nationally authorised product, the statement must be provided in case the pharmacovigilance system will be changed due to the transfer. For the medicinal products authorised via MRP/DCP, the document „*Q&A – List for the submission of variations according to Commission Regulation (EC) 1234/2008*“ published on the CMDh pages should be followed)** |
|[ ]  **dokaz o plaćenim troškovima postupka prijenosa odobrenja (za svako rješenje)****proof of payment of the procedural fee for the transfer (for each marketing authorisation)** |
|[ ]  **dodatna dokumentacija (ako postoji)****additional documentation (if any)** |

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| Potvrđujem da su navedeni podaci u ovom zahtjevu za prijenos odobrenja i u njegovim prilozima istiniti.I hereby confirm that the information provided in this application for the transfer of the marketing authorisation and its attachments is true and accurate. |
| Ime i prezime odgovorne/ovlaštene osobe dosadašnjeg nositelja odobrenja:Name of the responsible/authorised person of the current marketing authorisation holder: | Kliknite za upis | Click here to enter text. |
| Datum: Date: | Kliknite za odabir datuma | Click to enter a date. |
| Potpis:Signature: |