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

**APPLICATION FOR WITHDRAWAL OF MARKETING AUTHORISATION**

*NAPOMENA: jednim obrascem moguće je podnijeti više zahtjeva za više farmaceutskih oblika i/ili jačina istog lijeka*

*NOTE: a single application form may cover several applications for different pharmaceutical forms and/or strengths of the same medicinal product*

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 nositelju odobrenja za stavljanje lijeka u promet:**

**Marketing authorisation holder details:**

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| --- | --- |
| Naziv nositelja odobrenja za stavljanje lijeka u promet:  Name of the 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. **Obrazloženje zahtjeva za ukidanje odobrenja:**

**Explanation of the request for withdrawal of marketing authorisation:**

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

1. **Datum slanja Pokrovnog pisma i Tablice na e-mail adresu** [ukidanje@halmed.hr](mailto:ukidanje@halmed.hr) **u skladu s člankom 55. stavkom 2. Zakona o lijekovima (Narodne novine, br.** [76/13.](http://narodne-novine.nn.hr/clanci/sluzbeni/2013_06_76_1522.html), [90/14.](http://narodne-novine.nn.hr/clanci/sluzbeni/2014_07_90_1809.html) i [100/18.](https://narodne-novine.nn.hr/clanci/sluzbeni/2018_11_100_1931.html)):

**Date of sending the Cover letter and the Table to the e-mail address** [ukidanje@halmed.hr](mailto:ukidanje@halmed.hr) **according to the Article 55, paragraph 2 of the Medicinal Products Act (Official Gazette No.** [76/13.](http://narodne-novine.nn.hr/clanci/sluzbeni/2013_06_76_1522.html), [90/14.](http://narodne-novine.nn.hr/clanci/sluzbeni/2014_07_90_1809.html) and [100/18.](https://narodne-novine.nn.hr/clanci/sluzbeni/2018_11_100_1931.html)):

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| Kliknite za odabir datuma | Click to enter a date. |

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 nositelja odobrenja da ukidanje odobrenja za stavljanje lijeka u promet ne utječe na postizanje odgovarajućeg doziranja odobrenog u sažetku opisa svojstava lijeka i uputi o lijeku za jačinu i/ili farmaceutski oblik lijeka/ova istog imena s istom/im djelatnom/im tvari/ma istog nositelja odobrenja koji ostaje/u odobren/i, ako je primjenjivo**  **statement given by the marketing authorisation holder that the withdrawal of the authorisation does not affect achieving the appropriate dosing authorised in the summary of the product characteristics and the package leaflet for the strength and/or pharmaceutical form of the medicinal product(s) of the same name with the same active substance(s) of the same marketing authorisation holder which remain(s) authorised, if applicable** | |
|  | **dokaz o plaćenim troškovima postupka ukidanja odobrenja (za svako rješenje)**  **proof of payment of the procedural fee for the withdrawal (for each marketing authorisation)** | |
|  | **dodatna dokumentacija (ako postoji)**  **additional documentation (if any)** | |
| Potvrđujem da su navedeni podaci u ovom zahtjevu za ukidanje odobrenja i u njegovim prilozima istiniti.  I hereby confirm that the information provided in this application for the withdrawal of the marketing authorisation and its attachments is true and accurate. | | | |
| Ime i prezime odgovorne/ovlaštene osobe nositelja odobrenja:  Name of the responsible/authorised person of the marketing authorisation holder: | | Kliknite za upis | Click here to enter text. | |
| Datum:  Date: | | Kliknite za odabir datuma | Click to enter a date. | |
| Potpis:  Signature: | | | |