|  |  |  |
| --- | --- | --- |
| **Form** | | |
| **Transfer of authorisation** | | |
| **Identification number:** | ZL404\_00\_001 |
| **Version:** | 1.4 |
| **Valid from:** | 17.07.2023 |

# Basic information

|  |
| --- |
| **External reference (Company Reference):** …… |

# Addresses

## Marketing authorisation holder

|  |  |
| --- | --- |
| Company name: | …… |
| Addition: | …… |
| Street / no.: | …… |
| Postcode, town/city: | …… |
| Canton: | …… |
| Telephone: | …… |
| E-mail | …… |

## Address for correspondence (if not the same as 2.1)

|  |  |
| --- | --- |
| Company name: | …… |
| Addition: | …… |
| Street / no.: | …… |
| P.O. Box: | …… |
| Postcode, town/city: | …… |
| Telephone: | …… |
| E-mail | …… |

## Legal representative (if not the same as 2.1)

|  |  |
| --- | --- |
| Name: | …… |
| Addition: | …… |
| Street / no.: | …… |
| P.O. Box: | …… |
| Postcode, town/city: | …… |
| Telephone: | …… |
| **Does Swissmedic already possess the power of attorney?**  yes  no, the power of attorney is enclosed with this application (incl. original signature) | |

# Application type

|  |  |
| --- | --- |
| Transfer of the authorisation planned for:  (Deadline for submitting the application: at least 3 months before the planned date)  Shorter periods (less than 3 months) are only permitted in exceptional cases and must be justified below.  Reason:  °°°°° | °°°°° |
| Address of existing responsible authorisation holder: | |
|  | |
|  | |
|  | |
|  | |
|  | |

# List of medicinal products

|  |  |  |
| --- | --- | --- |
| **Authorisation no.** | **Name of the medicinal product[[1]](#footnote-1)** | **Dosage form** |
| °°°°° | °°°°° | °°°°° |
| °°°°° | °°°°° | °°°°° |
| °°°°° | °°°°° | °°°°° |
| °°°°° | °°°°° | °°°°° |
| °°°°° | °°°°° | °°°°° |

# Confirmations

|  |
| --- |
| The signatory hereby confirms that the requirements pertaining to the procedure for transferring the authorisation are satisfied, and will be implemented after the application has been approved, for all the medicinal products listed above. In particular:   * that, once the application has been approved by Swissmedic, responsibility for placing the medicinal product to be transferred on the market in its current authorisation status will also be transferred; * that, apart from the new name of the authorisation holder, no other changes of any kind will be made in connection with the application for transferring the authorisation; * that, once the application has been approved by Swissmedic, the only packaging elements and product information leaflets placed on the market will be those on which the new authorisation holder’s name has been printed in accordance with the requirements. Alternatively, the transitional arrangement[[2]](#footnote-2) of using adhesive labels can be implemented for no more than one year. * that the medicinal product information texts (Information for healthcare professionals and Patient information) will be published on the date the authorisation is transferred.   **Yes** |

# Logo and corporate design

Simultaneous modification of the logo or corporate design as part of an application to transfer the authorisation will be the responsibility of the authorisation holder. This means that it is not necessary to submit any documentation to Swissmedic for this purpose, provided the logo or corporate design has already been approved by Swissmedic at an earlier date.

If no logo or corporate design has been approved for the future authorisation holder, this will be evaluated as part of the transfer. A pack showing the logo or corporate design must be enclosed with the transfer application.

Swissmedic will only review the logo or corporate design (but not the other text on the pack) and no authorised text will be returned to the authorisation holder.

An additional fee based on the work involved will be charged for this evaluation.

Logo/corporate design not affected:

(Change to company name only, without any other changes to the typeface or design)

Logo/corporate design affected: ☐

The logo/corporate design has already been approved by Swissmedic. Yes  No

If no:

* Submit a pack showing the logo and corporate design for evaluation together with the application to transfer the authorisation. If the packaging elements have not yet been printed, the logo will be accepted on its own (in a PDF file).
* If Swissmedic already has the packaging as part of an application, please state the application ID: °°°°°

# Signature

|  |  |  |  |
| --- | --- | --- | --- |
| **All the entries made in this form are certified to be complete and accurate:**  *(company stamp of the applicant, optional)*  ……  ……  …… | | | |
| *Authorised signatory* | | *Other responsibilities (Optional signature)* | |
| Place, date: ……  Signature: …………………………….. | | Place, date: ……  Signature: …………………………….. | |
| Last name: | …… | Last name: | …… |
| First name: | …… | First name: | …… |
| Position: | …… | Position: | …… |
| Telephone: | …… |  | |
| E-mail | …… |
|  | | | |
| **The application must be sent to** | | **For enquiries contact** | |
| Swissmedic  Swiss Agency for Therapeutic Products  Operational Support Services  Hallerstrasse 7  3012 Berne | | Telephone +41 58 462 02 11  Fax +41 58 462 02 12  E-mail Anfragen@swissmedic.ch | |

Change history

| **Version** | **Change** | **sig** |
| --- | --- | --- |
| 1.4 | New layout, no content adjustments to the previous version. | dei |
| 1.3 | Changes to content regarding deadlines and logo/corporate design | gf, mb |
| 1.2 | Formal adjustments to the header and footer  No content adjustments to the previous version. | dei |
| 1.1 | Autor im System mit Autor in der Änderungshistorie synchronisiert. Freigabe durch Person im VM Team, da Dokument nicht in der VMS Suche angezeigt wird.  Keine inhaltlichen Änderungen | tsj |
| 1.0 | Implementation of HMV4 | dts |

1. A change to the name of the medicinal product is not possible in connection with the application for transfer of the authorisation. A separate application, which is subject to a fee, must be submitted to the Authorisation division at Swissmedic. [↑](#footnote-ref-1)
2. If the company makes use of the transitional arrangement, it is the company's responsibility to produce an adhesive label and to comply with the transitional period (a maximum of one year). [↑](#footnote-ref-2)