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| **Form** | | |
| **New authorisation for co-marketing medicinal product** | | |
| **Identification number:** | ZL108\_00\_002 |
| **Version:** | 3.1 |
| **Valid from:** | 30.06.2023 |

# Basic information

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| --- |
| **External reference (Company Reference): ……** |
| **Name of co-marketing medicinal product: ……** |
| **Name of basic product:……** |
| **Authorisation no. of basic product: ……** |
| **Active substance(s):** ……  *(Published on receipt of the application)* |
| **Medical application:** ……  *(For veterinary medicinal products incl. for each proposed targeted animal species)*  *(Published on receipt of the application)* |

# Addresses

## Authorisation holder of the co-marketing medicinal product for which authorisation is requested

|  |  |
| --- | --- |
| 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: | …… |
| **Swissmedic has received power of attorney**  yes  no\*  *\*If no: Power of attorney is enclosed with this application (incl. original signature)* | |

# Additional forms to be submitted

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| The form *Manufacturer information HMV4* is enclosed (must be submitted). |
| The form *Full declaration HMV4* is enclosed (must be submitted). |

# Further information

## Placing on the market

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| --- | --- |
|  | Intended for placing on the Swiss market |
|  | Intended for export only |

# Confirmations

## Confirmation of compliance with the requirements for the application documents

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| --- |
| The applicant for the co-marketing medicinal product confirms that the compilation of application documents satisfies the requirements of guidance document *Formal requirements HMV4* and the Directory *Overview of documents to be submitted HMV4*.  yes |

## eDok confirmation of identity (paper-based applications with eDok copy)

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| --- |
| The applicant confirms that the electronic copy and the paper documentation are complete and identical. The applicant hereby consents to the review being conducted by Swissmedic exclusively on the basis of the electronic documents.  yes  n/a |

## Dosage strengths

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| --- |
| The applicant confirms that the co-marketing medicinal product possesses the same dosage strengths as the basic product.  yes |

## Conformity of Information for healthcare professionals and Patient information with those for the basic product

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| --- |
| The applicant confirms that the medicinal product information conforms to the text of the Information for healthcare professionals and Patient information most recently approved by Swissmedic for the basic product …… (name of basic product) …… (month/year), apart from any deviations permitted by TPLRO.  yes |

## Packaging material / laser colour prints

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| --- |
| The applicant confirms that the enclosed laser colour prints for the above-mentioned product are completely identical to the original print of the packaging materials in terms of both text and graphic design.   yes  n/a |
| Imprint on solid dosage forms |
| The applicant confirms that the solid dosage form does not bear any imprint referencing the  basic product  yes n/a |

## Secondary packer

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| --- |
| Is/are the secondary packer(s) the same as that/those for the basic product?  yes  no  (If “no”, the additional/other secondary packer(s) must be declared on the form *Manufacturer information HMV4*.) |

# Signature

In signing this form, the signatories undertake to observe the following conditions:

* The **authorisation holder of the basic product** permits the scheduled **authorisation holder of the co-medicinal product** to rely entirely on the scientific documentation for the basic product in applying for authorisation of the co-marketing medicinal product. This permission will remain valid after the co-marketing medicinal product is authorised, particularly in respect of any variations to the basic product, which will also have to be implemented for the co-medicinal product within a specified period.
* The **person responsible for the manufacture** of the basic product hereby certifies that the basic product and its co-marketing medicinal product are absolutely identical (same manufacturing process, same qualitative and quantitative composition of the finished product in relation to active substances, excipients and primary packaging materials).
* The authorisation holder of the basic product, the authorisation holder of the co-marketing medicinal product and the person responsible for manufacture undertake to keep each other updated about the documentation and incidents relating to quality, efficacy and safety during use of both medicinal products. In particular, they undertaken to coordinate every application for a variation to both medicinal products. In order to safeguard public safety, Swissmedic reserves the right to forward required data or information concerning the basic product or co-marketing medicinal product to the authorisation holder of the basic product or the co-marketing medicinal product.

**Signature of applicant**

|  |  |  |  |
| --- | --- | --- | --- |
| **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: …………………………….. | |
| Name: | …… | Name: | …… |
| First name: | …… | First name: | …… |

**Signature of authorisation holder of the basic product**

|  |  |  |  |
| --- | --- | --- | --- |
| **All the entries made in this form are certified to be complete and accurate:**  *(company stamp of the authorisation holder, optional)*  ……  ……  …… | | | |
| *Authorised signatory* | | *Other responsibilities (Optional signature)* | |
| Place, date: ……  Signature: …………………………….. | | Place, date: ……  Signature: …………………………….. | |
| Name: | …… | Name: | …… |
| First name: | …… | First name: | …… |

**Signature of person responsible for manufacture**

|  |  |  |  |
| --- | --- | --- | --- |
| **All the entries made in this form are certified to be complete and accurate:**  *(company stamp, optional)*  ……  ……  …… | | | |
| *Authorised signatory (RP for galenical production or RP of the company issuing the batch certificate)* | | *Other responsibilities (Optional signature)* | |
| Place, date: ……  Signature: …………………………….. | | Place, date: ……  Signature: …………………………….. | |
| Name: | …… | Name: | …… |
| First name: | …… | First name: | …… |

|  |  |
| --- | --- |
| **The application must be sent to** | **For enquiries contact** |
| Swissmedic  Swiss Agency for Therapeutic Products  Operational Support Services  Hallerstrasse 7  3012 Bern | Telephone +41 58 462 02 11  Fax +41 58 462 02 12  E-mail Anfragen@swissmedic.ch |

Change history

| **Version** | **Change** | **sig** |
| --- | --- | --- |
| 3.1 | New layout, no content adjustments to the previous version. | dei |
| 3.0 | Amendment owing to changes to Guidance document on co-marketing of medicinal products | stb / wyk |
| 2.1 | Formal adjustments to the header and footer  No content adjustments to the previous version. | dei |
| 2.0 | Chapter 1: Addition information “Active substance(s)” and “Medical application” | fg |
| 1.2 | Chapter 3: Note on the declaration by the responsible person deleted. The form does not have to be submitted. | dts |
| 1.1 | Basic information: Deletion of the eCTD sequence no. | dts |
| 1.0 | Implementation of TPO4 | dts |