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| **Form** | | |
| **DMF** | | |
| **Identification number:** | ZL000\_00\_035 |
| **Version:** | 5.1 |
| **Valid from:** | 29.06.2023 |

# Addresses

## Marketing authorisation holder

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

## Address for correspondence (if not the same as 1.1)

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

## Legal representative (if not the same as 1.1)

|  |  |
| --- | --- |
| 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) | |

# Procedure for submitting DMFs

* The authorisation holder completes Part A of this form and sends a copy of the form (Parts A and B) to the DMF holder. The original, signed by the authorisation holder, is submitted to Swissmedic together with the application for new authorisation or variation. If several DMF holders are concerned, a separate form must be completed and submitted for each DMF holder.
* The DMF holder completes Part B of the copy of the form forwarded by the authorisation holder. The form (copy of Part A and the original of Part B) is submitted to Swissmedic directly, together with the covering letter, Letter of Access, Applicant's Part and Restricted Part.
* For applications according to Art. 13 TPA, the Assessment Report of the Restricted Part, the LoQ and the answers of the DMF holder relating to the Restricted Part should also be submitted.

# PART A (to completed by applicant / authorisation holder)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **The DMF is submitted for an application for:**  New authorisation  Variation | | | | |
| Active substance *(Latin name or INN):* ……  Name of DMF holder: ……  Country: ……  Telephone: ……  E-mail: …… | | | | |
| **Medicinal products concerned ( Human medicines  Veterinary medicines):** | | | |
| Authorisation no.  (*if known)* | Name of the medicinal product | Dosage form | Dosage strengths |
| …… | …… | …… | …… |
| …… | …… | …… | …… |
| …… | …… | …… | …… |

The authorisation holder confirms that the entries are accurate and acknowledges that, if the documents are not submitted correctly, they may be returned or disposed of in a controlled manner

|  |  |
| --- | --- |
| *Authorisation holder's authorised signatory***:**  Name, first name ……  Function …… | Place, date ……  Signature …………………………………………… |

# PART B (to be completed by DMF holder)

|  |
| --- |
| **DMF holder:**  Company name ……  Street ……  Postcode / town ……  Country ……  Enquiries: Name of contact: ……  Phone ……  E-mail …… |
| Manufacturing location *(name, address)*:  …… |
| Active substance *(Latin name or INN)*:  …… |
| The version and date for this DMF are:   * Applicant's part: Version …… Date: …… * Restricted part: Version …… Date: …… |
| The DMF is being submitted to Swissmedic for the first time.  The DMF replaces that of (version no. or submission / creation date): ……  For applications for variations: tabular compilation of variations ("approved to date" / "proposed") enclosed.  The DMF has already been submitted for other medicinal products, with the following Swissmedic DMF no.  (*if known):* ……  The DMF will be/has been submitted to one of the following drug regulatory authorities:  Australia, DMF#: ……  Canada, DMF#: ……  Singapore, DMF#: ……  EMA, ASMF#: …… |

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| **Other medicinal products authorised in Switzerland with the same DMF**  **( Human medicines  Veterinary medicines):** | | | | |
| Authorisation no.  (*if known)* | Name of the medicinal product | Dosage form | Dosage strengths | |
| …… | …… | …… | …… | |
| …… | …… | …… | …… | |
| …… | …… | …… | …… | |
|  | | | |

## Sharing information with partner authorities

|  |
| --- |
| ***Human medicinal products*** The DMF holder permits Swissmedic to share the evaluation reports that it draws up on this DMF within the framework of collaboration with partner authorities of the International Regulators Consortium (Therapeutic Goods Administration of Australia, Health Products and Food Branch of Canada, Health Sciences Authority of Singapore and Healthcare Products Regulatory Authority of United Kingdom), based on existing agreements for the purpose of sharing information and as support for forming opinions. Accordingly, Swissmedic is authorised to provide its evaluation reports relating to this DMF on request1. The decision regarding an authorisation is made independently of any information sharing with Swissmedic.  yes  no  n/a  ***Veterinary medicinal products***  The DMF holder permits Swissmedic to share the evaluation reports that it draws up on this medicinal product within the framework of the collaboration with partner authorities (Ireland: HPRA / Health Products Regulatory Authority; Canada: Health Canada; Austria: AGES / Agency for Health and Food Safety) based on [existing agreements](https://www.swissmedic.ch/ueber/01398/01401/01936/index.html?lang=en) for the purpose of sharing information and as support for forming opinions. Swissmedic is thus authorised to provide its evaluation reports to partner authorities on request1. The decision regarding an authorisation is made independently of any information sharing with Swissmedic.  yes  no  n/a  Swissmedic informs the applicant in writing if evaluation reports are shared.  *1 These evaluation reports may contain confidential data, such as personal data, business secrets and both positive and negative evaluations with regard to the assessment of an authorisation.* |

## Information sharing in the context of processing risk evaluations on nitrosamine impurities

|  |  |  |
| --- | --- | --- |
| |  | | --- | | The DMF holder permits Swissmedic to share with international partner authorities assessments drawn up by Swissmedic on nitrosamine impurities in a medicinal product within the scope of participation in the Nitrosamine Strategic Group (NISG) and the Nitrosamine Technical Working Group (NITWG) for the purpose of sharing information and as support for forming opinions. This exchange is based on the existing agreements ([www.swissmedic.ch/informationaustausch](https://www.swissmedic.ch/swissmedic/en/home/about-us/international-collaboration/bilateral-collaboration-with-partner-authorities/agreements-on-information-exchange.html)). Swissmedic is thus authorised to provide its assessments to partner authorities1. The decision regarding an authorisation is made independently of any information sharing with Swissmedic.  Agreement of DMF holder ☐ yes ☐ no  1 *These assessments may contain confidential data, such as personal data, business secrets and both positive and negative evaluations with regard to the assessment of an authorisation.* |   The DMF holder confirms that the entries are accurate and the documents complete, and acknowledges that, if the documents are not submitted correctly, they may be disposed of in a controlled manner (DMF holder abroad) or returned at the applicant's expense, in the latter case only if the domicile of the DMF holder is in Switzerland: | |
| **DMF holder**  **Responsible Person:**  Last name, first name ……  Function …… | Place, date ……  Signature …………………………………………… |

Change history

| **Version** | **Change** | **sig** |
| --- | --- | --- |
| 5.1 | New layout, no content adjustments to the previous version. | dei |
| 5.0 | Part B: Contact for enquiries added to address section for DMF holders. | dts |
| 4.0 | Part B: Incorporation of DMF holder’s agreement to information exchange re. risk assessments for nitrosamine impurities as section 4.2  Subsections 4.1 and 4.2 for clearer structure | stb |
| 3.0 | Part B: Repositioning of the checkboxes and the text regarding information about the exchange with the Consortium  UK included in the list of Consortium countries | nma |
| 2.2 | 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 |
| 2.1 | PART B (to be completed by DMF holder): Deletion of the eCTD-Sequence. | dts |
| 2.0 | Explanation of the procedure for submitting DMFs. | nma |
| 1.0 | Implementation of TPO4 | dts |