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| **Form** | | |
| **Status of authorisation applications abroad** | | |
| **Identification number:** | ZL000\_00\_030 |
| **Version:** | 3.0 |
| **Valid from:** | 01.04.2024 |

# Basic information

|  |  |
| --- | --- |
| Name of the medicinal product: | …… |
| Authorisation no.: *If known* | …… |
| Application ID:  *If known* | …… |
| Date: | …… |

# Further information

## Authorisation status of the application in the foreign country

The status must be specified for the following countries/authorities:

* EMA authorisation applications (CP, DCP, MRP)
* National authorisation applications in EU / EFTA countries
* Authorisation applications in USA / Canada / Australia / New Zealand / Japan / Singapore

|  |  |  |  |
| --- | --- | --- | --- |
| Approved | Country / countries | Date of approval | Name of the medicinal product |
|  | …… | …… | …… |
| Submitted | Country / countries | Date of submission | Name of the medicinal product |
|  | …… | …… | …… |
| Withdrawn | Country / countries | Date of withdrawal | Name of the medicinal product |
|  | …… | …… | …… |
| Suspended\* | Country / countries | Date of suspension | Name of the medicinal product |
|  | …… | …… | …… |
| Rejected\* | Country / countries | Date of rejection | Name of the medicinal product |
|  | …… | …… | …… |

*\* including Switzerland, if a request to take the evaluation results of foreign authorities into consideration (Art. 13 TPA) was submitted.*

In the case of new authorisation applications and indication extensions, the indication wording approved abroad should be stated (English or correspondence language):

|  |  |  |
| --- | --- | --- |
| **Country** | **Wording of the approved indication** | **Remark** |
| …… | …… | …… |
| …… | …… | …… |
| …… | …… | …… |

|  |
| --- |
| Are there any final Assessment Reports from the above-mentioned authorities/countries?  the final Assessment Reports[[1]](#footnote-1) are attached to the application.  yes, but the final Assessment Reports are not attached to the application.  🡪 If not attached, please state reasons in the covering letter  no |

Change history

| **Version** | **Change** | **sig** |
| --- | --- | --- |
| 3.0 | In the case of new authorisation applications and indication extensions, the indication wording approved abroad should be stated (not only in the case of wordings that differ). | sab |
| 2.1 | New layout, no content adjustments to the previous version. | dei |
| 2.0 | Explanation regarding the EMA Assessment Reports: no EPAR (footnote) | stb |
| 1.1 | Author in system synchronised with author in the change history. Approved by person in VM Team as document is not displayed in the VMS search.  No changes to content. | tsj |
| 1.0 | Implementation of TPO4 | dts |

1. EMA authorisation applications: complete Assessment Reports, no EPAR [↑](#footnote-ref-1)