**State Agency of Medicines of Latvia**

**Application**

**for**

**Scientific Advice**

Please fill in this form to apply for the scientific advice from the State Agency of Medicines of Latvia (hereafter – the Agency).

The completed form with annexes should be sent to *info@zva.gov.lv*. In the *subject* line please indicate: Scientific advice and product name.

Additional information on the scientific advice procedure please see in the [Scientific Advice Guideline](https://www.zva.gov.lv/en/node/5633)

1. **Applicant:**

|  |  |  |
| --- | --- | --- |
| **Company name:** |  | |
| **Registration number:** |  | |
| **Address:** |  | **Phone number:**  **E-mail:** |
| **Bank details:** |  |  |
| **Contact person:** |  |  |
| **Job title:** |  |

1. **Contact person for financial matters** (please fill in if differ from the above):

|  |  |  |
| --- | --- | --- |
| **Company name:** |  | |
| **Registration number:** |  | |
| **Address:** |  | **Phone number:**  **E-mail:** |
| **Bank details:** |  | |

1. **Information about the product:**

|  |  |
| --- | --- |
| **INN and trade name (if applicable):** |  |
| **Indication (for the scope of this SA):** |  |
| **ATC code:** |  |
| **Type:** | □ Chemical  □ Biological  □ Herbal |
| **Pharmaceutical form:** |  |
| **Dispensing legal status:** | □ Prescription  □ OTC  □ Not yet established |
| **Is this product currently marketed in any EU country?** | □ Yes, please specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_  □ No |
| **Intended marketing authorization procedure:** | □ National  □ MRP  □ DCP  □ CAP |
| **Is this product currently under assessment in any other EU country?** | □ Yes, please specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_  □ No |

1. **Information about sought scientific advice:**

|  |  |
| --- | --- |
| **The advice is related to a prospective:** | □ Clinical trial authorization  □ Marketing authorization  □ Health technology assessment  □ Variations  □ Other, please specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Area of advice**  **(please tick all necessary)** | □ Regulatory questions  □ Pharmaceutical quality  □ Non-clinical data/studies  □ Pharmacokinetics  □ Efficacy/safety data/studies  □ Statistics  □ Pharmacovigilance/ Risk management plan  □ Pharmacoeconomics  □ Other, please specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Please outline questions you intend to submit for this scientific advice:** | |
| **Has other scientific advice been requested or is in process on this product?** | □ Yes  □ No |
| **If yes, please provide details on the received advice and submit related documents:** | |
| **Other comments:** | |

1. **Annexes:**

|  |  |
| --- | --- |
|  |  |
|  |  |
|  |  |

|  |
| --- |
| * Within 7 days you will be notified to the specified email address if the application can be accepted. * If the Agency accepts to provide the scientific advice, you will be sent an invoice and asked to send complete documentation via CESP or by email to [info@zva.gov.lv](mailto:info@zva.gov.lv). * The scientific advice (a report providing answers to each question) will be sent to you via email to the specified email address within 8 weeks after payment and complete documentation is received. * By signing below, I acknowledge that I have read and agree to the scientific advice procedure and I declare, that all of the information I have provided is complete and correct. |
|  |

|  |  |  |
| --- | --- | --- |
| First name, last name |  | |
| Job title |  | |
|  |  | |
| (place, date) |  | (signature) |
|  |  |  |