**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:**

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| --- | --- |
| **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:**

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| --- | --- |
| **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:**

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