**Application for Scientific Advice (Consultation) provided by Marketing Authorisation Section of SÚKL**

Please send the completed form to the email address: posta@sukl.gov.cz or to the data box of the State Institute for Drug Control (henceforth “SÚKL”).

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| Administrative data |
| Date of request |       |
| Proposed form of Scientific Advice | [ ] written [ ] oral  |
| Proposed date of Scientific Advice |       |
| Expected duration of Scientific Advice |       |
| Is it a follow up Scientific Advice? | [ ]  yes sukls:      [ ]  no |
| Was submission of the Scientific Advice requested by SÚKL? | [ ]  yes[ ]  no |

SME status: [ ]

(refer to guideline [UST-29](https://sukl.gov.cz/en/about-us/guidelines-and-forms/general-guidelines/) - [Instructions for payment of expenses and administrative charges – SÚKL](https://sukl.gov.cz/en/about-us/tariff-and-fees/instructions-for-payment-of-expenses-and-administrative-charges/))

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| Contact information |
| Company/applicant |       |
| Contact person  |       |
| Phone |       |
| E-mail |       |
| Address |       |
| List of participants and their experties/position |       |

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| Information relating to the medicinal product |
| Name of the medicinal product\*  | Name of the active substance | ATC code\*  |
| (Proposed) Indication | Pharmaceutical form, Method of Administration |
| Marketing authorisation number\*  |
| Origin of the active substance*[ ]*  chemical*[ ]* biological*[ ]* biotechnological*[ ]* herbal*[ ]* other |
| Phase in which the product currently is *(several options may be marked)**[ ]* Pharmaceutical development of the product*[ ]* Pre-clinical study*[ ]* Clinical study*[ ]* Authorised product |
| Area covered by the requested scientific advice-required SÚKL expert opinion *(several options may be marked)*[ ]  Quality[ ]  Quality – „Process Analytical Technology“ (PAT)[ ]  Pre-clinical evaluation or trial[ ]  Clinical evaluation or trial[ ]  Pharmacokinetics[ ]  Pharmacovigilance[ ]  Statistics – clinical, pre-clinical data[ ]  Change of legal status[ ]  Procedural-regulatory[ ]  Other - please specify |
| (Proposed) legal basis of registration (according to directive 2001/83/EC)[ ]  Art. 8.3 Stand –alone marketing authorisation[ ]  Art. 10.1 Generic marketing authorisation[ ]  Art. 10.3 Hybrid marketing authorisation[ ]  Art. 10.4 Similar biological marketing authorisation[ ]  Art. 10a Well Established Used marketing authorisation[ ]  Art. 10b Fixed combination[ ]  Art. 10c Informed consent[ ]  Art. 14 Homeopathic product[ ]  Art. 16a Traditional herbal product | Type of application[ ]  Application for marketing authorisation[ ]  Line Extension[ ]  Variation to marketing authorisation[ ]  Renewal of marketing authorisation[ ]  Other - please specify |
| States where the product is authorised\* *:*  | (Proposed) legal status:[ ]  OTC[ ]  RX |

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| **List of questions from the applicant and responses from SÚKL** |
| **Is this a consultation prior to application for marketing authorisation?** |
| [ ]  no[ ]  yes – type of marketing authorisation:  *[ ]* national *[ ]* DCP – RMS *[ ]* MRP/RUP – RMS *[ ]* DCP – CMS *[ ]* MRP/RUP – CMS *[ ]* Centralised procedure |
| **Please select the area covered by the requested scientific advice, state your queries and positions. Erase those parts of the questionnaire that are not applicable.** |
| **Quality** |
| 1.Query:      1. Applicant´s position:      2. Query:      2. Applicant´s position:      … |
| **Pre-clinical** |
| 1.Query:      1. Applicant´s position:      2. Query:      2. Applicant´s position:      … |
| **Pharmacokinetics** |
| 1.Query:      1. Applicant´s position:      2. Query:      2. Applicant´s position:      …  |
| **Clinical efficacy** |
| 1.Query:      1. Applicant´s position:      2. Query:      2. Applicant´s position:      … |
| **Clinical safety** |
| 1.Query:      1. Applicant´s position:      2. Query:      2. Applicant´s position:      … |
| **Pharmacovigilance** |
| 1.Query:      1. Applicant´s position:      2. Query:      2. Applicant´s position:      … |
| **Statistics (pre-clinical and clinical data)** |
| 1.Query:      1. Applicant´s position:      2. Query:      2. Applicant´s position:      … |
| **Change of Legal Status** |
| 1.Query:      1. Applicant´s position:      2. Query:      2. Applicant´s position:      … |
| **Procedural-regulatory queries** |
| 1.Query:      1. Applicant´s position:      2. Query:      2. Applicant´s position:      … |
| **Other** |
| 1.Query:      1. Applicant´s position:      2. Query:      2. Applicant´s position:      … |

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| **Appendices** |
| ***E.g.*** explanation of the issue involved; overview of requests; study protocols; results from other consultations if such scientific advice has already been sought on the given subject; relevant legislative sources etc.      |

**Note:** The Scientific Advice is not legally binding either for the SÚKL or the applicant, neither at the time that it is provided nor for any future SÚKL position relating to the submitted queries. This consultation is provided on the basis of currently valid regulatory requirements and scientific knowledge. The responses of the SÚKL are based on the queries submitted by the applicant and the submitted documentation and they need not reflect any future changes in scientific progress and regulatory requirements. The applicant takes into account that this consultation is provided regardless of any future submitted registration documentation and contained substantiated details for purposes of authorisation of the product in question and regardless of the intellectual property of third parties. The minutes/output/written conclusion of the consultation must be appended to the subsequent application for which it was provided (as Annex 5.14 of Module 1 of documentation).

**Information for applicants:**  SÚKL processes the provided data for the purpose of conducting administrative proceedings with the applicant, on the basis of Section 13, Paragraph 2 of the Act on Medicinal Products. For more information on the processing of personal data can be found on the website [SÚKL](https://sukl.gov.cz/en/) in the section Personal data protection.