

Requirements set forth by Section 37, paragraph 2 of Act No 500/2004 Coll., the Code of Administrative Procedure, as amended – particulars of an application:

- Identification of the administrative authority to which the application is addressed – in this case, SÚKL
- Identification of the applicant – legal entity
 - Name
 - Registered office (and mailing address, if needed)
 - Company registration number (ID no.) (or another similar identifier)
 - Name, surname + address (permanent residence or mailing address, where applicable) and date of birth of the statutory body acting on behalf of the legal entity (unless the legal entity acts via an authorised representative)

If represented, then:

 - Name + registered office (and mailing address, if needed) + ID no. (or a similar identifier) of the representative (if a legal entity)
 - Name, surname, address (permanent residence or also mailing address, if needed) and date of birth (if a natural person)
 - In either case, provide information on the power of attorney + the date when it was executed
- Identification of the applicant – natural person
 - Name, surname
 - Address (permanent residence, and also mailing address, if needed)
 - Date of birth

If represented, then:

 - Name + registered office (and mailing address, if needed) + ID no. (or a similar identifier) of the representative (if a legal entity)
 - Name, surname, address (permanent residence or also mailing address, if needed) and date of birth (if a natural person)
 - In either case, provide information on the power of attorney + the date when it was executed
- File ID/reference number of the decision granting the marketing authorisation of the medicinal product (identification of the marketing authorisation of the medicinal product concerned by the Sunset Clause)
- Name and marketing authorisation number of the medicinal product concerned by the application
- In the application, the applicant shall state their exact proposal, i.e. what they apply for in their application and reasons for it, and shall support their application by relevant source materials/evidence (to be listed) justifying the claimed facts stated in the application (if needed)
- Signature of authorised person (i.e. the statutory body or authorised representative)