Requirements governing applications pursuant to Section 37, paragraph 2 of Act No 500/2004 Coll., Administrative Code, as amended – particulars of application:

- Specification of the administrative authority to which the application is addressed – in this case it is SÚKL

- Identification of the applicant – legal entity (PO)
  - Name
  - Registered office (or another mailing address)
  - Company identification number (IČ – or adequate identifier)
  - First name, surname + address (permanent residence or mailing address, if applicable), and date of birth of the statutory body, (unless the PO acts via an authorised representative), who acts on behalf of the PO

  If represented, then:
  - Name + registered office (or another mailing address) + Company identification number (IČ – or adequate identifier) of the representative (if the representative is a PO)
  - First name, surname, address (permanent residence or mailing address, if applicable), and date of birth (if the representative is a natural person)
  - In both cases it is essential to provide information on the Power of Attorney + the date of its execution

- Identification of the applicant – natural person (FO)
  - First name, surname
  - Address (permanent residence or another mailing address, if applicable)
  - Date of birth

  If represented, then:
  - Name + registered office (or another mailing address) + Company identification number (IČ – or adequate identifier) of the representative (if the representative is a PO)
  - First name, surname, address (permanent residence or mailing address, if applicable), and date of birth (if the representative is a FO)
  - In both cases it is essential to provide information on the Power of Attorney + the date of its execution

- File identifier/reference number of the marketing authorisation of the medicinal product
- Identify the marketing authorisation of the medicinal product to which the Sunset Clause pertains
- Marketing authorisation number of the medicinal product which has been specified in the marketing authorisation
- Name + identification of the medicinal product in respect of which the application is submitted

- In the application, the applicant shall state their exact proposal, i.e. what they request by their application, and shall provide relevant background materials (to be listed) supporting the fact which is the subject matter of the application
- Signature of authorised person (i.e. of the statutory body or authorised representative)