

POWER OF ATTORNEY – General Information

Powers of Attorney submitted to SÚKL are governed exclusively by the Czech legislation and shall be interpreted in accordance with the Czech legislation.

Representation based on a Power of Attorney allows a natural or legal person who is a party to a procedure to be represented by another natural or legal person for the purposes of the concerned procedure. The Power of Attorney is given by the principal (a party to a procedure or applicant) to an agent (the person to represent the former). In each Power of Attorney, the principal shall be obliged to clearly and concisely define the extent of the authorisation. For a single matter, the party to the procedure may only have one agent at a time. This means that based on Powers of Attorney, the principal may not authorise two or more agents to the same extent. Should such collision occur, the latest Power of Attorney shall be considered to revoke the former Power of Attorney.

A Power of Attorney may be given to a natural or legal person. With regard to the extent of the Power of Attorney, it is possible to distinguish among Powers of Attorney intended for:

- 1) a specific act, group of acts or a particular part of the procedure;
- 2) the entire procedure;
- 3) an unspecified number of procedures concerning a specific subject-matter to be commenced within a specific period of time or in the future without limitations (so called “presidial” Power of Attorney); in such a case, the principal’s signature on the Power of Attorney must always be officially certificated and until the start of the procedure, the Power of Attorney shall be kept with the administrative authority competent *ratione materiae* (i.e., the Power of Attorney shall not be applicable to previously initiated administrative procedures);
- 4) another extent on the basis of a special act.

When acting on behalf of the principal, the agent shall have the right to be represented by another person only if explicitly permitted to do so by the principal in the Power of Attorney (in so called substitution clause). Such relationship is known as substitution and requires granting of yet another, so-called substitution Power of Attorney. The extent of substitution representation cannot be greater than that of the original Power of Attorney containing the substitution clause.

With a view to the aforementioned, it is hence the party to the procedure, or its authorised representative, or (if the Power of Attorney allows for substitution) the substitution representative who acts vis-à-vis the administrative authority in the administrative procedure.

It is necessary to distinguish between a Power of Attorney and an authorisation. In an authorisation, a legal person authorises its employee to act in an administrative procedure on behalf of the legal

person, i.e., on behalf of the latter's employer. Unlike in a Power of Attorney, in such a case, it is the legal person who continues to act vis-à-vis the authority as the party to the procedure, acting via its authorised employee. Thus, the party to the procedure is not represented by another person (as in the case of a Power of Attorney), and acts through its authorised employee. The advantages of an authorisation are as follows: it does not require any official certification of the principal's signature and it is possible to authorise more than one employee of the concerned company. In a single matter, however, only one person may act for the legal person at one time.

Mandatory particulars of a Power of Attorney:

- **Principal**
 - principals-natural persons shall be identified by: name and surname, address of residence, date of birth;
 - principals-legal persons shall be identified by: company name, registered office of the company as per the Companies Register, company registration number (IČO).
- **Agent**
 - agents-natural persons shall be identified by: name and surname, address of residence, date of birth;
 - agents-legal persons shall be identified by: company name, registered office of the company as per the Companies Register, company registration number (IČO).
- **Extent of the Power of Attorney** (i.e., what the principal empowers the agent for)
- **Principal's signature** (Powers of Attorney of principals-legal persons shall be signed by the principal's statutory body)
- **Date of principal's signature**
- **Official certification of the principal's signature** – physical as well as electronic official certification of the signature (only if required for the Power of Attorney in question; see section 3 above; official certification details are explained below)

Official certification:

Legalisation: an official certification of the authenticity of the signature; if official certification of the principal's signature is required for the Power of Attorney (see point 3 above), only the principal (not the agent) shall have the signature on the Power of Attorney certified; where a Power of Attorney from abroad is submitted, the legalisation shall be thereafter certified by an apostille or superlegalisation.

Apostille: a certification of the authenticity of the signature issued by the competent authority of the state that is a party to The Hague Apostille Convention of 5 October 1961. A foreign Power of Attorney with an attached apostille may then be used without any further verification within the territory of any party to the Convention and before any of its authorities. If the Power of Attorney is properly completed, it certifies the authenticity of the signature, the position of the person who signed the Power of Attorney, and, if applicable, the authenticity of a seal or stamp attached to the Power of Attorney. The apostille, however, does not certify the veracity of the content of the Power of Attorney to which it is attached. For those countries who are not parties to The Hague Convention, it is necessary to conduct superlegalisation at the embassy or consulate of the respective country.

Superlegalisation: a higher degree of Power of Attorney certification by means of which a Power of Attorney to be presented abroad is certified. It is required in any country that is not a party to The Hague Apostille Convention. Superlegalisation means certification of the authenticity of signatures and official stamps and seals on such Power of Attorney.

Superlegalisation is based on the principle of double certification. A public instrument (document) is initially certified by the concerned authority, i.e., the Ministry of Foreign Affairs of the concerned state where the Power of Attorney has been signed. Thereafter, the consulate of the country where the document is to be used, conducts so called higher certification or superlegalisation. The document, superlegalised as mentioned above, is then ready for use in the Czech Republic, but it must be complemented with an official translation into the Czech language.

Vidimation: an official certification attesting that the copy of the document is verbatim identical to the presented document (original).

Methods of Power of Attorney submission

In the form of a **copy** (also in electronic format as part of the submitted documentation; documents signed with an electronic signature may only be submitted in the form of an electronic original): applies only to Powers of Attorney intended for the purposes of:

- 1) a specific act, group of acts or a particular part of the procedure;
- 2) the entire procedure (*e.g. for the concerned application for marketing authorisation or variation to marketing authorisation of a medicinal product*).

In the form of an **original or officially certified copy of an original:** this form is required for presidential Powers of Attorney, i.e., a Power of Attorney for an unspecified number of procedures concerning a

particular subject-matter that are to be commenced within a predefined period of time or without restriction in the future.

Delivery

Documents in an administrative procedure **are delivered** (on the part of the administrative authority) to the authorised representative. (Deliveries to legal persons in the Czech Republic are made electronically, to the data mailbox; deliveries to legal persons abroad are made in paper form by post; deliveries to natural persons in the Czech Republic are made in paper form by post or electronically to the person's data mailbox – deliveries to natural persons may not be made to the data mailbox of a legal person or a natural person-entrepreneur; deliveries to natural persons-entrepreneurs in the Czech Republic are made exclusively to the data mailbox of the respective natural person-entrepreneur). In case representation by an agent is employed, deliveries cannot be made directly to the represented person – principal (except for exemptions set forth by law).

A Power of Attorney may be terminated by:

- 1) the completion of the act to which it was restricted;
- 2) revocation by the principal;
- 3) notice submitted by the agent;
- 4) death of the agent or principal, where natural persons are concerned;
- 5) death of the agent or principal, where legal persons are concerned.

The Power of Attorney may be revoked by the principal at any time. The revocation of the Power of Attorney shall be effective for the agent as of the moment the agent learnt of it.

Electronic signatures

The State Institute for Drug Control accepts submissions, documents, Powers of Attorney signed with a recognised or qualified electronic signature. Documents signed with a recognised or qualified electronic signature must be submitted as electronic originals, so that it is possible to verify the authenticity of the electronic signature.

The relevant provisions governing electronic signatures are contained in Sections 5 and 6 of Act No 297/2016 Coll., on trust services for electronic transactions:

Section 5

Only a **qualified electronic signature** may be used to sign documents by means of electronic signature in those cases where the signature is attached to an electronic document by means of which:

a) the state, local or regional authorities, legal persons established by law, or legal persons established or founded by the state, a local or regional authority or by a legal person established by law or their body or another unit (hereinafter referred to as the “signatory governed by public law”) carry out an act or

b) a person not listed under letter (b) carries an act in the execution of its powers.

Section 6

(1) Only a recognised electronic signature may be used to sign documents by means of electronic signature in those cases where the signature is attached to an electronic document by means of which an act vis-à-vis a signatory governed by public law or vis-à-vis another person in association with the execution of their powers is being carried out.

(2) A recognised electronic signature shall mean an advanced electronic signature based on a qualified certificate for the electronic signature or a qualified electronic signature.

EU Regulation:

Regulation (EU) 910/2014 of the European Parliament and of the Council of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC

Other concepts:

Substitution: representation of the agent by another person.

Example of a substitution clause: *On the basis of a substitution Power of Attorney, the agent may authorise another person to act on behalf of the agent in the extent of the agent’s empowerment stipulated by the Power of Attorney.*

Power of Attorney effective date: A Power of Attorney shall become effective as of the date of its delivery to SÚKL.