

Contracted representation – powers of attorney

Anyone, be it a natural or legal person, when of full legal capacity, is eligible to gain rights and undertake obligations for itself through its own legal acting, i.e. to legally act.

It is assumed that everyone primarily acts on their own behalf. The law allows for a person to act on behalf of another one and determines rules governing such set-up. If regulated entities decide to act through their representative, it is appropriate for them to familiarise themselves in advance with rules which govern acting on behalf of someone else.

The legal background for acting on behalf of another person in relation to an administrative authority is set forth by:

the Civil Code – particularly Sections 436-488 of Act No 89/2012 Coll. (hereinafter referred to as the “Civil Code”) – lex generalis (general provisions)

and by

the Administrative Code - Sections 30-35 of Act No 500/2004 Coll., as amended (hereinafter referred to as the “Administrative Code”) – lex specialis (special provisions).

Below please find some information in case you decide to appoint a representative to communicate with SIDC (SÚKL) on your behalf, rather than acting directly yourself. This information will help you navigate through the aforementioned legal background, but it is not to be considered as an interpretation of the said provisions or their complete overview.

As SÚKL is an administrative authority, relations in this area are governed by the Czech Administrative Code, and therefore also acting on behalf of another person is subjected particularly to those provisions of the Administrative Code which govern representation.

1. Consequences of representation

If a regulated entity decides to appoint a representative to act on their behalf (contracted representation), it should be aware of the following:

- the representative will act on their behalf and through such acting rights and obligations will arise directly for the regulated entity = the represented entity;
- it is necessary to be aware of who may and who may not act as the representative (conflict with the interest of the represented entity) and to know what the consequences of the representative's acting are;
- representation affects also the deliveries of written documents – the administrative authority delivers only to the representative (except for cases where the represented entity is to conduct something in the procedure personally);
- for a single matter, a party to administrative procedure may have only one representative;
- in compliance with the Administrative Code, the authority to act on behalf of someone is to be evidenced by means of an original written power of attorney;
- some powers of attorney require an authenticated signature – see below;
- a subsequently presented power of attorney revokes a previously presented one (i.e. a newer one revokes an older one), within the scope in which they overlap (i.e. if there is a power of attorney for the scope of representation in administrative procedures

- regarding price and reimbursement issues, and later, a general power of attorney for another representative is presented, then this newer power of attorney revokes the original one);
- if the power of attorney does not clearly specify the scope of representation, the representative shall be considered authorised to act on behalf of the represented person within the entire procedure (Section 34 of the Administrative Code).

The following terms are used in the text below:

principal - meaning the person of the represented entity, i.e. the regulated entity who issues the power of attorney;

agent – meaning the person of the representative, i.e. whoever acts on behalf of the regulated entity.

If SÚKL receives a power of attorney, it enters the information implied by this document into SÚKL's information system. If this information is inaccurate or misleading, or if the power of attorney does not meet the requirements applicable thereto pursuant to Section 33 of the Administrative Code, SÚKL will inform the person who presented the power of attorney to evidence its authorisation to act, or the principal (in the administrative procedure by means of an invitation to eliminate shortcomings of the submission).

Where inaccurate data are presented, it may subsequently cause problems, e.g. during delivery, if the agent is not clearly identified or if it is not clear what the mailing address is. Problems in delivery may then be associated with adverse consequences, such as expiry of timelines for the conduct of process acts.

With a view to the aforementioned, please draft the submitted powers of attorney carefully.

2. What is a power of attorney?

A power of attorney informs third parties that entities specified therein have agreed that one is to act on behalf of the other, and it informs about the scope of the representation authorisation.

Pursuant to the Administrative Code, authorisation is to be evidenced by means of a written power of attorney.

The power of attorney therefore has to clearly identify

- a) who the principal (represented entity) is;
- b) who the agent (the person who represents) is;
- c) the scope of representation authorisation.

a) Identification of the principal

In case the principal is:

- **A legal person** – it shall be identified by means of its name, the identification number (IČ) or another similar registration number, registered office, i.e. data incorporated in the Commercial Register or another similar registry or other record system specified by law;
For example, it is hence not possible to provide the actual place of business of the legal person, but always only the registered office specified in the Commercial Register;
- **A natural person** – it shall be identified by its full name (name + surname), date of birth, address of permanent residence. In a power of attorney for acts associated with its entrepreneurial operation, a natural person shall state the name and surname, and, if applicable, a supplement distinguishing the person of the entrepreneur or the type of business associated with this person or to the type of business operated thereby, the

identification number of the person and the address incorporated in the Commercial Register or another registry referred to by law as its place of business.

b) Identification of the agent

The same applies to the agent. **The power of attorney shall always clearly indicate whether the agent is a natural or legal person.** An organisational part of an enterprise cannot be an agent, as, according to the Civil Code, it does not have a legal personality.

In this respect, powers of attorney tend to be unclear or specify the agent as both a natural and legal person which is not possible according to the Administrative Code (e.g. *an employee of a company who is not the principal at the same time, i.e. a natural person is identified by the name and registered office of a legal person – in this case it is not obvious whether the principal wishes to authorise the natural or legal person*). It is always necessary to specify only one, clearly identifiable agent.

The identification of the agent is important as in case of representation written documents are delivered only to the agent and only such delivery affects the expiry of timelines. Provision of inaccurate or even incorrect data in a power of attorney could hence result in failure to deliver the document to the hands of the agent. Eventually, this could lead e.g. to a situation when the agent does not learn about the delivered document.

Therefore, please pay attention to the identification of the agent.

The same as specified under item a) hence applies to the identification data, i.e.

Where the agent is:

- **A legal person** – it shall be identified by means of its name, the identification number (IČ) or another similar registration number, registered office, i.e. data entered in the **Commercial Register** or another similar registry or other record system specified by law;
- **A natural person** – it shall be identified by its full name, date of birth, address of permanent residence. In a power of attorney for acts associated with its entrepreneurial operation, a natural person shall state the name and surname, and, if applicable, a supplement distinguishing the person of the entrepreneur or the type of business associated with this person or to the type of business operated thereby, the identification number of the person and the address incorporated in the Commercial Register or another registry referred to by law as its place of business.

c) The scope of representation authorisation

This shall mean the scope of authority, i.e. specification of acts which the agent will be authorised to carry out on behalf of the principal – it may vary. The Administrative Code distinguishes among the following groups:

- a) Section 33, paragraph 2 letter a) of the Administrative Code – for a specific act, group of acts or for a certain part of the administrative procedure

For example: “*to view the file maintained in the administrative procedure*”, *to waive the right of repeal, to file a repeal within administrative procedure file no. suklsXXXX/2009, to submit an application for determination of the amount and conditions of reimbursement of medicinal product XY, SÚKL code 11111 or to communicate within the scope of the national phase of marketing authorisation procedure regarding medicinal product XY, DCP number XX/H/XXXX/XXX/DC;*

- b) Section 33, paragraph 2(b) of the Administrative Code – for one entire specific procedure

For example: *for administrative procedure regarding the determination of the maximum price of medicinal product XY, SÚKL code 11111111, or for representation in administrative*

procedure regarding administrative offence maintained at SÚKL, for several entire specific procedures – e.g. for administrative procedure regarding variation to marketing authorisation of a medicinal product no. 1 and administrative procedure regarding variation to marketing authorisation of a medicinal product no. 2 (in such a case, several separate administrative procedures are concerned, but instead of submitting several separate powers of attorney - one for each procedure – it is possible to draft a single power of attorney. PLEASE NOTE – do not confuse this type with the type specified under item c) below.

- c) Section 33, paragraph 2(c) of the Administrative Code – for an indefinite number of procedures regarding a certain subject-matter, which are to be commenced within a specified period of time or without limitation, in respect of which the agent will be authorised (so called general power of attorney, general authorisation).

For example: "to act in relation to SÚKL in marketing authorisation procedures for specified medicinal product XY, marketing authorisation number XX/XXX/XX-C, in any procedures regarding specified medicinal product XY, SÚKL code 11111, representation in administrative procedures regarding prices and reimbursements of medicinal products."

Pursuant to the provisions of Section 33, paragraph 2(c) of the Administrative Code, such power of attorney, i.e. one granted under item c), has to bear an officially authenticated signature of the principal. In these cases please pay attention also to information provided below regarding official authentication of signatures - legalisation, and the difference from vidimus.

The Administrative Code specifies yet another type of scope of a power of attorney – a different scope pursuant to a special law.

d) Other data in a power of attorney

A power of attorney may, furthermore, specify the following:

- the period of time for which representation has been contracted (i.e. the authority is limited in time);
- **the mailing address**, i.e. the power of attorney may specifically detail an address other than the address of the registered office or permanent residence of the agent (*e.g. the agent is a natural person, but the delivery address may be the address of the registered office of a legal person*);
- it may be specified that the agent may grant a power of attorney to another person to act on the party's behalf for the agent (**substitution representation**) in compliance with the provision of Section 33, paragraph 3 of the Administrative Code. If this is not specified in the power of attorney, the agent may not choose their representative. If substitution representation is contracted and the principal asks the administrative authority to deliver to the substitution agent, the substitution power of attorney has to explicitly state that the substitution agent is the person who has been authorised also for the receipt of written documents, i.e. the scope of the power of attorney will explicitly include also deliveries.

A power of attorney shall always be dated and signed by the principal, in some cases (item c) refers), the principal's signature has to be officially authenticated.

If the power of attorney has been issued in electronic format, it has to be signed with a recognised electronic signature. In compliance with the provisions of Act No 286/2014 Coll., the authority may be granted also via the Registry of Medical Devices.

In some cases, powers of attorney are submitted to SÚKL in an attachment to a submission sent via a data mailbox. In such a case the power of attorney regarding representation has to be signed by the principal. A power of attorney in the form of an electronic document shall be either signed with a certified electronic signature of the principal, or it will be an authorised conversion output as referred to by Act No 300/2008 Coll. The power of attorney shall contain an authentication clause (Section 22).

- e) In compliance with Section 16 of the Administrative Code, powers of attorney are to be submitted **in the Czech or Slovak language**. Pursuant to Section 16, paragraph 2 of the Administrative Code, **SÚKL shall also accept powers of attorney in the English language**. If, however, the power of attorney is submitted in a language other than the above-mentioned ones, then the original of the power of attorney in the foreign language together with an officially certified translation into the Czech language have to be submitted, as required by Section 16, paragraph 2 of the Administrative Code.

3. Powers of attorney in scope referred to by Section 33, paragraph 2(c) of the Administrative Code

If a regulated entity decides to grant a power of attorney in a scope defined by Section 33, paragraph 2 letter c) of the Administrative Code, i.e. for an indefinite number of procedures of a certain subject-matter which are to commence within a specified period of time or without limitation (so called general power of attorney, general authorisation), the conditions set forth by the Administrative Code have to be met, in particular: the principal's signature has to be officially authenticated – the authentication of the signature (legalisation) must not be confused with vidimus (official attestation of a document). Legalisation is the verification of authenticity of the signature. Legalisation confirms that the signing person signed the document in their own hand. Vidimus, on the contrary, is a verification attesting that the presented document and its copy are identical. The original of the document is usually one. If, however, it is necessary to submit an original of the document, but the submitter also wishes to keep the original, they have the copy of the document vidimated – officially attested. A copy with the power of an original is thus obtained. This will concern e.g. *powers of attorney for any communication with SÚKL regarding all marketing authorisation procedures, or regarding all procedures in respect of variations to marketing authorisations for a specific medicinal product, for all acts in administrative procedures conducted in compliance with the Act on Public Health Insurance on prices and reimbursements of medicinal products and foods for special medical purposes, etc.*

These powers of attorney are stored in the Institute and the regulated entity does not have to document them for any performed act again. The assessment of the power of attorney is hence completed once, upon its submission, which facilitates smooth course of administrative procedures. It is sufficient to deliver the original (or officially attested copy – see above) of such "general power of attorney" to SÚKL only once. Such power of attorney thereafter may be used for an indefinite number of procedures regarding a certain subject-matter which are to be commenced within a specified period of time or without limitation (Section 33, paragraph 2 letter c) of the Administrative Code), or for a particular type of procedure which is specified in the general power of attorney, e.g. administrative procedure regarding marketing authorisation, administrative procedure regarding prices and reimbursements, etc. In case the principal selects a different agent for each administrative procedure or legal act, an original of the power of attorney must be always submitted to and reviewed by the administrative authority and assessed thereby in terms of its impact upon powers of

authorisations submitted previously. It is always completely up to the principal to select the scope of the representation authorisation. Nevertheless, also the correct selection of the scope of the representation authorisation (i.e. exact definition of the scope of the representation authorisation in case where various agents have been engaged for various administrative procedures) may contribute to the smooth course of the administrative procedure.

4. Clinical trials on human medicinal products and sponsor's agent

The provision of Section 51, paragraph 2(d) of Act No 378/2007 Coll., on Pharmaceuticals and on Amendments to Some Related Acts (Act on Pharmaceuticals), as amended, stipulates that a sponsor may only be such person who resides or is established within a Member State, or a person who has appointed an authorised representative compliant with this condition.

This authorised representative identifies itself by a power of attorney. Such power of attorney is subjected to the same rules as mentioned above. The issue of representation in the area of clinical trials is detailed in SÚKL's guideline KLH 20, version 5, Annex 3 and 4.

5. Revocation of power of attorney

If the principal decides to terminate contracted representation, it should forthwith inform SÚKL to this effect. This fact will be reflected by SÚKL in further acts, particular in terms of deliveries, only as of the time this information is delivered to the SÚKL.

Please deliver the information on termination of contracted representation to SÚKL in writing. This information has to contain an exact identification of the person who revokes the power of attorney and an exact identification of the revoked power of attorney. The Institute stores a large number of powers of attorney and the submitted information has to provide for exact identification of the power of attorney to be revoked and hence taken out of the records. With a view to the aforementioned, the information should contain as much information on the submitted power of attorney as possible – who authorised whom in what scope and on what date, as well as the date when the agent learnt of the termination of contracted representation. The rules governing the identification of the agent and of the principal are identical to those applicable to the granting of the power of attorney. Where the principal is a legal person, the information must be signed by an individual appointed to act for the legal person. If the granting of the power of attorney is endorsed with an officially authenticated signature, it is advisable to have the information on the revocation of the power of attorney also signed in this manner, i.e. the signature should be officially authenticated. It is, however, not necessary to revoke a power of attorney in each case, as the submission of a later (newer) power of attorney overrides the previous (older) power of attorney within identical scope, i.e. replaces the latter in the same scope.

6. Acting of a legal person through its employee – so called appointment (Letter of Authorization)

If the regulated entity – legal person decides to act on their own behalf, acts shall be carried out in its name by whoever has been appointed to act so in a court procedure, i.e.

- a) a member of the statutory body; if the statutory body comprises of several individuals, the chairperson or a member appointed thereby shall act for the legal person; if the chairperson or the appointed member is a legal person, the acts shall be carried out always by a natural person appointed or otherwise authorised by the legal person to do so, or
- b) its employee (member) who has been appointed by the statutory body for this purpose; or
- c) the manager of its branch where matters pertaining to this branch are concerned; or
- d) its chief clerk, if, according to the granted power of procuration he/she may act independently;
- e) another person set forth by a special law.

This implies that acts on behalf of a legal person may be conducted - as is often the case in practice - by a legal person via its employee. The employee has to evidence his/her appointment by an **authorisation (Letter of Authorization)**. In such a case the authorisation has to clearly indicate that

it concerns an act of the legal person proper which is carried out by its employee, and that it does not concern contracted representation (it does not concern a power of attorney). In these cases it is advisable to explicitly state in the authorisation that it is an employee of the company (principal). The company as well as the appointed employee should be clearly identified (the company using the same data as for the principal, the appointed employee using his/her name, surname, and position performed thereby, date of birth, and address of permanent residence).

Whoever carries out any act has to evidence their authorisation to act (Section 30, paragraph 5 of the Administrative Code).

Only one person may act on behalf of the legal person in one matter at one time. The authorisation may specify more than one person, but it is necessary to clearly identify when each of the persons is to act. They cannot be authorised to act at the same time.

A clear distinction between an appointment and a power of attorney is relevant for the deliveries of documents. Where contracted representation (power of attorney) is concerned, the SÚKL is obliged to deliver to the address of the agent. Where acting via an appointed employee of a legal person is concerned, the SÚKL is obliged to deliver to the address of the legal person or to the data mailbox of the legal person, where Czech entities are concerned.

For this reason, please make a clear distinction between an appointment (Letter of Authorization) and a power of attorney in your submissions. An appointment may be securely distinguished from a power of attorney by a statement in the appointment that the natural person acting for the principal is the principal's employee.

7. Powers of attorney and appointments in case of written agreement referred to by the provision of Section 39a, paragraph 2(b) (Agreement on Highest Ex-factory Price – AHEP) and by the provision of Section 39c, paragraph 2(d) (Agreement on Reimbursement – AoR) of Act No 48/1997 Coll., on Public Health Insurance, as amended

Where powers of attorney or appointments for the conclusion of AHEPs/AoRs are concerned, SÚKL notifies of the fact that these powers of attorney and appointments are not subjected to the regimen set forth by the Administrative Code, but fall within the sphere of civil law, and therefore have to be drafted accordingly. In general, the aforementioned may be used for the identification of the principal and of the agent, but in terms of the scope of the representation authorisation, it has to be worded in the civil law context, ideally with the identification of a specific civil law act (conclusion of a written agreement). With a view to the aforementioned, for example the general power of attorney submitted in compliance with the provision of Section 33, paragraph 2(c) of the Administrative Code, etc. cannot be accepted for the conclusion of AHEPs/AoRs.

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