

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 a natural or legal person decides to act through its representative, it is appropriate for it to familiarise itself 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 an agent to communicate with 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 an interpretation of the said provisions or their complete overview.

As SÚKL is an administrative authority, relations in this area are governed by the 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 natural or legal person decides to appoint a representative to act on their behalf (contracted representation), it should be aware of the following:

- the representative will act on its behalf and through such acting rights and obligations will arise directly for the represented person = principal;
- it is necessary to be aware of who may and who may not act as an agent (conflict with the interest of the represented person) 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 agent (except for cases where the represented person is to conduct something in the procedure personally);
- for a single matter, a party to administrative procedure may have only one agent;
- some powers of attorney need to be signed with an authenticated signature and submitted in the original – 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 agent 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 agent shall be considered authorised to act on behalf of the principal within the entire procedure (Section 34 of the Administrative Code).

The following terms are used in the text below:

- **principal** - meaning the represented person, 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 natural or legal person
- **power of attorney** – meaning the document which informs third parties that the entities specified therein agreed that one of them is to represent the other and which informs of the scope of the representation authorisation. Pursuant to the Administrative Code, such mandate is evidenced by means of a written power of attorney.

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 obvious 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. Power of attorney

The power of attorney has to clearly identify:

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

a) Identification of the principal, if 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 **Companies Register** or another similar registry or other record system specified by law; it is hence not possible to provide the actual registered office of the legal person, but always only the registered office specified for the legal person in the Companies 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 with the type of business operated thereby, the identification number of the person and the address incorporated in the Companies Register or another record system referred to by law as its place of business.

b) Identification of the agent

The same identification requirements as those applicable to the principal apply to the agent. **The power of attorney shall always clearly indicate whether the agent is a natural or legal person.** An organisational unit of a company 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 particular 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.

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(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 appeal 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 in SÚKL, for several entire specific procedures – e.g. for administrative procedure regarding variation to marketing authorisation of medicinal product no. 1 and administrative procedure regarding variation to marketing authorisation of medicinal product no. 2 (in such a case, several separate administrative procedures are concerned, but instead of filing 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 the future; in this case, the signature attached to the power of attorney shall always be authenticated and the power of attorney shall be kept in SÚKL or, if applicable, stored in the protocol, until the start of the procedure. Where a natural or legal person decides to grant a power of attorney within the aforementioned scope, the conditions set forth by the Administrative Code for this type of power of attorney must be met, in particular:

- Submission of the original or an officially attested copy of the original (vidimation = verification attesting that the copy is verbatim identical to the presented document - original)
- Authentication of the principal’s signature (legalisation)
- Storage of the power of attorney in SÚKL until the start of the procedure

These powers of attorney are kept on SÚKL’s records outside individual administrative procedures and the agent does have to re-submit them for each legal act, i.e. for each act conducted, including initiation of the administrative procedure, to evidence its authorisation to act on behalf of the principal. The assessment of the power of attorney is hence completed once, upon its submission. Thereafter, officials retrieve data about the agent from this submitted power of attorney, which contributes to a smooth course of the administrative procedure.

This concern, for example, “acting before SÚKL in marketing authorisation procedures of the said medicinal product XY, M A n u m b e r XX/XXX/XX-C; a n y procedures regarding a specific medicinal product XY, SÚKL code 11111; representation in administrative procedures regarding prices and reimbursements of medicinal products.”

Such powers of attorney have to be stored in SÚKL until the start of the procedure. Their submission does not imply any change to the agents of the party to the procedure in respect of pending procedures. If the party to the procedure changes its agent in the course of the administrative procedure and, at the same

time, wishes to avail of the institute of a power of attorney issued in compliance with Section 33, paragraph 2(c) of the Administrative Code, it may approach the situation e.g. as follows:

- It may submit a power of attorney referred to under this provision (i.e. within the scope for an indefinite number of procedures with a particular subject-matter which are to be initiated within a specified period of time or without limitation; the power of attorney shall bear an officially authenticated signature of the principal and the power of attorney is to be submitted in the original);
- And, concurrently, it shall submit a power of attorney issued pursuant to Section 33, paragraph 2(b) of the Administrative Code, where it shall identify all of the pending procedures in respect of which the agent is being changed. This power of attorney does not have to be submitted in the original and does not have to bear an officially authenticated signature. Nevertheless, it must allow for a clear identification of the particular administrative procedure(s) for which it is being submitted.

d) Section 33, paragraph 2(c) of the Administrative Code – a different scope pursuant to a special law (e.g. Act No 85/1996 Coll., on the Legal Profession 85/1996, as amended).

e) 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*);
- **substitution** – 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 its 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.

f) **A power of attorney shall always be dated with the date of issue 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 shall be considered signed if signed with as simple signature. Should a legal regulation require an authenticated signature of the principal, the power of attorney shall be submitted in the form of a paper document (original or an attested copy).

3. 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 Institute.

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 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. 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.

4. Acting of a legal person through its employee – so called appointment

If a legal person decides to act on its 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 always carried out 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 its chief clerk, if, according to the granted power of procuration he/she may act independently;
- d) 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. 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, and, where appropriate, 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 essential for the deliveries of documents. Where contracted representation (power of attorney) is concerned, SÚKL is obliged to deliver to the address of the agent. Where acting via an appointed employee of a legal person is concerned, 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 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.

5. 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 submitted, 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, the scope 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, cannot be accepted for the conclusion of AHEPs/AoRs, etc.

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 shall be 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.

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