

## Information for applicants on applicability of the new Administrative Procedure Code

The State Institute for Drug Control informs that with effect from 1 January 2006 its activities will be governed by the new Administrative Procedure Code (Act No. 500/2004 Coll., as amended). This Act or its relevant provisions shall be applied in cases when special legal regulations, e.g. Act no. 79/1997 Coll., on Pharmaceuticals, as amended, or Act no. 123/2000 Coll., on Medical Devices, as amended, do not set forth specific provisions for the procedure in question. The new Administrative Procedure Code brings a number of new provisions which will contribute to accelerated and simplified processing of all well grounded requests. The Code lays down unambiguous rules for the authorities and also certain new duties for applicants. Therefore, all applicants are kindly asked to introduce the new features into practice and thus make the mutual communication smoother and contribute to successful and fast processing of all requirements. As before, the information which should help provide unambiguous interpretation and fast introduction of all new provisions into practice will be published on the SUKL website.

The main new provisions are as follows:

- a) Section 33 (1) of the Administrative Code provides that each **participant may have simultaneously only one authorised representative in the same case.**

As of today, SUKL registers a number of letters authorising various persons to act on behalf of a single company which set out no limitation on executing their powers; it means that there are two or more representatives authorised to perform acts in the same administrative proceedings. After 1 January 2006, this is, however, in contradiction to the above provision. Due to that we ask all applicants/ marketing authorisation holders who have submitted a Letter of Authorisation to the Institute to remove this potential discrepancy because in such cases the administrative proceedings may be unnecessarily delayed due to time spent on clarification and removal of such contradiction to the law. The Annex gives guidance for issuing authorisations and model examples. Any questions and information related to this issue should be addressed to [posta@sukl.cz](mailto:posta@sukl.cz).

- b) Section 30 (5) of the Administrative Code provides that **each person that performs acts in the proceedings must provide an evidence of his/her power to take part in the proceedings.**

Applicants are hereby asked to comply with this provision (see Annex). In case that a Letter of Authorisation has been already submitted to the Institute we try to facilitate the situation by considering the requirement laid down by Section 30 (5) of the Administrative Procedure Code as fulfilled, if this fact is explicitly notified to the Institute with reference to the date of submission of the relevant Letter of Authorisation.

- c) Section 19 (3) of the new Administrative Procedure Code provides that a participant to the proceedings **may be served documents via electronic mail**, except when this is excluded by statute or by nature of the case in question. **The participant, however, must apply for such e-mail service.**

If you are interested in this way of acceleration please send your application for e-mail service of documents related to administrative proceedings to the Institute including the relevant e-mail address either in writing, signed by the person empowered to act on behalf of the applicant, or by e-mail with the secured electronic signature of that person. Such service may be requested also for proceedings that may be open in future before the same administrative body. Kindly address your applications to [posta@sukl.cz](mailto:posta@sukl.cz).

- d) Section 16 (1) of the new Administrative Procedure Code lays down rules for the official language of proceedings. Proceedings are held and documents are executed in the Czech language, participants may act and submit documents also in the Slovak language. The new

Administrative Procedure Code provides that any foreign language document submitted within administrative proceedings shall be submitted simultaneously both as an original and its officially certified translation into Czech. **The State Institute for Drug Control hereby declares that in accordance with Section 16 (2) of Act No. 500/2004 Coll., such translation will not be required when the document is submitted in English.**

## **Representation under the Letter of Authorisation**

Participants to proceedings may be represented by a legal entity or natural person. Authorisation to act on behalf of another person shall be evidenced by a **written Letter of Authorisation**. The new Administrative Procedure Code lays down that every person who performs acts in administrative proceedings shall provide an evidence of his/her empowerment. [(Sec.30 (5)].

Letter of Authorisation may be issued to a

- a) Legal entity – when a Letter of Authorisation is issued to a legal entity (without specifying who is the person charged to act on behalf of the legal entity in that particular case) then this legal entity may be represented only by the person empowered to act on behalf of the legal entity (see below),
- b) Natural person.

By issuing the Letter of Authorisation the authorising person declares against third persons that there is an internal relationship based on representation agreement between him/her and the authorised person. The Letter of Authorisation must clearly indicate

- a) who is the person issuing the Letter of Authorisation (identification data), i.e. who is the authorising person;
- b) who is the person accepting the authorisation (identification data), i.e. who is the authorised representative;
- c) scope of authorisation and, where applicable, time limitation;
- d) the Letter of Authorisation must bear the authorising person's own signature.

The Letter of Authorisation takes effect at the moment it is handed to the authorised representative.

**The acts performed by the authorised representative constitute rights and obligations for the authorising person.** Letter of Authorisation must bear a signature of the person empowered to act on behalf of the authorising person. In case of submissions related to marketing authorisation this signature must be certified by a notary public (see Regulation no. 288/2004 Coll.) in other cases a personal signature is sufficient (e.g. for Letters of Authorisation submitted within clinical trials approval procedures a notarised signature is not required).

Representation under the Letter of Authorisation shall be distinguished from **deeds of persons who are empowered to act on behalf of a legal entity**, e.g.

- a) a person or body empowered to legally bind the legal entity;
- b) an employee charged to act on behalf of the legal entity by a) above;
- c) director of structural unit (if registered in the Commercial Register);
- d) proctor (if empowered to act independently by virtue of his procuration);
- e) other persons under special circumstances – e.g. official receiver;
- f) head of a state agency or an employee charged by him/her;
- g) for self-governing territorial units (regions) a person authorised by special statute to act on behalf of the region, employee or authorised councillor.

Under b), f) and g) a letter certifying that the employee may act on behalf of the legal entity should be submitted.

Apart from the above, **activities of contact persons** should be distinguished. **These persons are not authorised to perform acts in administrative proceedings on behalf of the applicant**, however, they may forward information e.g. by e-mail in order to speed up administrative proceedings for instance in mutual recognition procedure. These persons, however, cannot act on behalf of a participant to the proceedings, documents shall not be served on them etc.

Examples:

*Model situation A:*

ABC Company whose person empowered to act on its behalf is Mr Brown submits an application to SÚKL. The application is signed by Ms Nice, an employee of ABC Company.

The application should be accompanied by a letter certifying that Ms Nice, employee of ABC Company, may act on behalf of this company. This letter shall be signed by Mr Brown and it may state that e.g. according to internal regulations Ms Nice is empowered to perform certain acts on behalf of ABC Company.

*Model situation B:*

XYZ Ltd, an applicant whose person empowered to act on its behalf is Mr. Smith, wants to be represented by ABC Company whose person empowered to act on its behalf is Mr Brown.

An application signed by Ms Nice, employee of ABC Company, is submitted to SÚKL.

The application form should clearly indicate the above facts and should be accompanied by:

- a) Letter of Authorisation issued by XYZ Ltd to ABC Company authorising ABC Company to act on behalf of XYZ Ltd. in that particular case. This Letter of Authorisation must be signed by Mr Smith.
- b) Letter certifying that Ms Nice, employee of ABC Company, may act on behalf of this company. This letter must be signed by Mr Brown, see model situation A.