

This form is not intended for completion. Please use this template as a guidance when issuing a letter of authorisation.

LETTER OF AUTHORISATION

..... (insert details of the Authorising Person, i.e. person granting the authorisation, e.g.

- MAH (marketing authorisation holder), if the medicinal product is authorised,
- the importer or domestic manufacturer of foods for special medical purposes;
- the importer or domestic manufacturer of the medicinal product, if the medicinal product imported or manufactured thereby is used on the territory of the Czech Republic within the scope of a specific therapeutic programme, or another applicant for a specific therapeutic programme;
- persons referred to in Section 39f of Act No 48/1997 Coll., on Public Health Insurance, as amended

give the applicant's name, registered address, ID number and other identification details)

(hereinafter "the Authorising Person")

hereby in compliance with Sections 33 and 34 of Act No 500/2004 Coll., the Administrative Procedure Code, as amended, authorises

(Note: It is necessary to distinguish between an authorisation referred to in Section 33 and Section 34 of the Administrative Procedure Code and an authorisation referred to in section 30, paragraph 3 of the Administrative Procedure Code. This should always be clearly indicated in the document.)

..... (insert details of the Authorised Person, either:

- LEGAL ENTITY** – i.e. a company – give the name of authorised company, its registered address, ID number and other identification details ; or
- NATURAL PERSON** – i.e. Mr/Ms – give full name(s) of the authorised person, his/her address, other identification data may be included when applicable

(hereinafter "the Authorised Representative")

(Note: Pursuant to the provisions of Section 33, paragraph 1 of Act No. 500/2004 Coll., the Administrative Procedure Code, as amended, which has been effective in the Czech Republic since January 1, 2006, a party to an administrative procedure may have only ONE AUTHORISED REPRESENTATIVE AT ONE TIME!!

If the authorising person authorises a natural person and identifies him/her by name, surname and address, correspondence will be delivered to this particular address. Where the authorising person wishes to have correspondence delivered to another address (so called contact address), he/she shall mention this fact in the Letter of Authorisation. It may also be communicated subsequently by the authorised person.)

to

(the scope of authority, i.e. specification of the acts that the authorised person will be entitled to carry out on behalf of the authorising person – this may vary

a) for a specific act, suite of acts or for a specific part of administrative procedures (e.g. for “inspecting the dossier maintained within the scope of the administrative procedure”, waiving the right to appeal, filing an appeal with respect to the administrative procedure ref. no. suksXXXX/2009, for submitting a request for the determination of the level and conditions of reimbursement of medicinal product XY, code 111111

b) for an entire single specific procedure, e.g.:

for an administrative procedure concerning the determination of the maximum price of medicinal product XY, code 11111111;

for an administrative procedure concerning a change to the determined maximum price of medicinal product XY, code 11111111;

for an administrative procedure concerning cancellation of the determined maximum price of medicinal product XY, code 11111111;

for an administrative procedure concerning the determination of the level and conditions of reimbursement of medicinal product XY, code 11111111;

for an administrative procedure concerning a change to the determined level and conditions of reimbursement of medicinal product XY, code 11111111;

for an administrative procedure concerning the cancellation of the determined level and conditions of reimbursement of medicinal product XY, code 11111111;

etc. (furthermore, joint procedures may be applicable)

c) for an unspecified number of procedures concerning a specific subject matter which are to be commenced in the specified period or without limitation, for which the authorised person will be authorised.

(Note: Pursuant to the provisions of Section 33, paragraph 2 (c) of Act No. 500/2004 Coll., the Administrative Procedure Code, as amended, effective since January 1, 2006, the signature on the Letter of Authorisation assigned within the scope defined by item (c) must be officially authenticated.)

(Note: - Pursuant to the provisions of Section 33, paragraph 3 of Act No. 500/2004 Coll., the Administrative Procedure Code, as amended, effective since January 1, 2006, the authorised representative may assign the authority to another person to act on their behalf only if the Letter of Authorisation explicitly states that the authorised representative may do so.)

This fact must be stated in the instrument, e.g.:

The Authorised Representative may delegate this authorisation to another person to represent him/her in full scope of authorisation granted by the Letter of Authorisation.

This other authorisation, however, must clearly show that the other authorised person will act on the basis of this very substitution authorisation.

Signed in Prague on this day of ... (date of execution of the Letter of Authorisation)

.....

Legible name and surname of the Authorising Person and his/her personal signature
(The signature must be certified by a notary and the Letter of Authorisation must be signed by the person authorised to act on behalf of the Authorising Person, e.g. a corporate agent, proctor, empowered person, member of the board of directors etc.)

Declaration of the Authorised Representative that he/she accepts the appointment, assumes the fiduciary and other legal responsibilities, including date (not mandatory) may be added below, e.g.:
I accept my appointment as the Authorised Representative under this Letter of Authorisation.

.....

Date and signature of the Authorised Representative