Power of attorney

Information on the submission of the power of attorney documents has been divided into national and European procedures (MRP/DCP). Similar requirements apply under the national and European procedures (MRP/DCP) with a few exceptions which are listed at the end of this document.

National procedure

Procedures concerning:

- variations to marketing authorisation and marketing authorisation dossier pursuant to Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products
- variations pursuant to the Regulation of the Minister of Health of 12 May 2014 on variations to marketing authorisation and marketing authorisation dossier
- variations pursuant to Article 31(1c) of the Pharmaceutical Law of 6 September 2001 (hereinafter the "Pharmaceutical Law"), the so-called '*notifications*'
- change of the Marketing Authorisation Holder (Article 32 of the Pharmaceutical Law)
- change of the decision pursuant to Article 155 of the Act of 14 June 1960 Code of Administrative Procedure
- renewal of a marketing authorisation
- withdrawal of a marketing authorisation
- other post-approval procedures related to a marketing authorisation

1. **A document identifying the person authorized to act on behalf of the Marketing Authorisation Holder should be submitted with each application.**

The following person(s) can be authorized to act on behalf of the Marketing Authorization Holder:
a) attorney(s)
b) commercial attorney(s)
c) person(s) indicated in the register of entrepreneurs as authorized to represent the Marketing Authorization Holder

If the Marketing Authorisation Holder is represented by an attorney, the application shall be accompanied by a document that provides the power of attorney and an extract from the relevant register of entrepreneurs.

The attorney shall submit the power of attorney with the first action taken in the procedure.

An attorney representing the Marketing Authorisation Holder have to be a natural person with legal capacity. The Marketing Authorisation Holder cannot be represented by another company.

The power of attorney should specify whether or not the attorney is authorized to grant further powers of attorney.

The power of attorney may be general (e.g. to act on behalf of the MAH in proceedings regarding medicinal products) or special (e.g. to act on behalf of the MAH in specific proceedings).

The extract from the register of entrepreneurs should specify the person(s) authorized to represent the Marketing Authorisation Holder and to grant the power of attorney. If the power of attorney has been signed by a person who does not appear in the extract from the register of entrepreneurs, the application shall be accompanied by a power of attorney for the person signing the power of attorney.

If the Marketing Authorization Holder acts through a commercial attorney, the application should be accompanied by an extract from the relevant register of entrepreneurs. See also section 4.

If the Marketing Authorisation Holder is represented by a person or persons indicated in the register of entrepreneurs as authorized to represent the MAH, the application should be accompanied by an extract from the relevant register of entrepreneurs.

The rules for submitting documents from the register of entrepreneurs are laid out in a separate document.

2. The form and format of the power of attorney.

The power of attorney should be granted in writing and submitted as:
- electronic document signed with a qualified electronic signature, trusted signature or personal signature, or
- hard-copy document signed with a handwritten signature.

The attorney shall submit original power of attorney or official copy thereof.

A copy of the power of attorney may be certified by:
- notary public;
- lawyer, legal advisor, patent attorney, tax advisor, if the power of attorney has been issued for these persons.

A copy of the document may be submitted as electronic document signed with a qualified electronic signature, trusted signature or personal signature, or as a hard-copy document signed with a handwritten signature.

Documents signed with an electronic signature (qualified, trusted, personal) should be submitted in electronic form.

Documents signed with a handwritten signature (originals) should be submitted in hard copy.

3. The power of attorney should be in Polish.

If the power of attorney is made in a language other than Polish, such document must be accompanied by a translation into Polish. The translation should be certified by a sworn translator (original or official copy of the translation).

The Polish translation of the power of attorney may be submitted as:

- electronic document with a qualified electronic signature of a sworn translator,
- hard-copy document with a handwritten signature of a sworn translator.

It is acceptable to submit a power of attorney drawn up in two languages – Polish and foreign (one document containing two language versions of the power of attorney).

4. The power of attorney or commercial power of attorney shall be accompanied by a proof of payment of stamp duty.

Stamp duty shall be charged for submission of a power of attorney, commercial power of attorney or extract, excerpt or copy thereof.

The stamp duty is PLN 17 for each power of attorney (commercial power of attorney).

If more than one person is granted the power of attorney under a single document, the stamp duty shall be a multiple of PLN 17 (e.g. number of persons x PLN 17).

If the Marketing Authorisation Holder acts through a commercial attorney, a stamp duty shall be charged for submission of the document providing the commercial power of attorney i.e. an extract from the register of entrepreneurs. The stamp duty applies for the commercial representation relationship which is expressed by submitting the document confirming commercial power of attorney (the amount of the stamp duty does not depend on the number of commercial attorneys entered in the register). The submission of an extract from the register of entrepreneurs is subject to a fee only when the document is submitted in order to demonstrate that the power of attorney was granted to a person to act in the case concerned.

For a joint power of attorney or a joint commercial power of attorney, the fee is PLN 17 per document providing the (commercial) power of attorney.

For a substitute power of attorney, stamp duty is charged for submitting the power of attorney on the basis of which the attorney will act in the case concerned.

A stamp duty should be paid to the bank account of the competent tax authority (Warsaw City Hall; for more information please visit: http://www.urpl.gov.pl/pl/opłaty).

5. Attorney for service

Regardless of granting a general or special power of attorney to act in the case, the Marketing Authorisation Holder may appoint an attorney for service.

The Marketing Authorisation Holder should appoint a attorney for service in Poland if the attorney of the Marketing Authorisation Holder has indicated an address outside the European Union or the European Free Trade Association (EFTA) as the address for service.

Letters in paper form will not be sent to address outside the European Union or the European Free Trade Association (EFTA). If no attorney for service is appointed in Poland, such letters will be left in the case files with the effect of delivery.

<u>European procedures (MRP/DCP)</u>

I. Procedures concerning:

- variations pursuant to Article 31(1c) of the Pharmaceutical Law (the so-called '*notifications*')
- change of the Marketing Authorisation Holder (Article 32 of the Pharmaceutical Law)
- change of the decision pursuant to Article 155 of the Act of 14 June 1960 Code of Administrative Procedure
- withdrawal of a marketing authorisation
- other post-approval procedures related to a marketing authorisation, made on a national level

- the rules governing the foregoing procedures are the same as in the national procedure.

II. Procedures concerning:

- variations to marketing authorisation and marketing authorisation dossier pursuant to Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorizations for medicinal products for human use and veterinary medicinal products;
- variations according to Article 61(3) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use
- renewal of a marketing authorisation

- the rules governing the foregoing procedures are the same as in the national procedure with the following exceptions:

1) The document granting the power of attorney should be made in Polish or English. If the document is not in Polish or English, it must be accompanied by translation into Polish or English. The translation should be certified by a sworn translator.
2) The power of attorney for a variation application should be submitted according to footnote 6 eAF (electronic application form).
3) In case of post-authorisation variations, a scan of the power of attorney attached with documentation submitted in eCTD format via CESP is considered acceptable (i.e. copies of hard-copy documents signed with a handwritten signature are accepted).

History of changes:
1.0 – 08.04.2021 – first version
1.1 – 01.03.2024 – correction in point 3 (adjustment to the Polish version); addition of point 5; editorial changes