Extract from the register of entrepreneurs

Information on the submission of documents from the register of entrepreneurs 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
- 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 a person authorized to represent the Marketing Authorisation Holder should be submitted for each procedure**

An extract from the relevant register of entrepreneurs should be submitted to identify the person authorised to represent the Marketing Authorisation Holder.

The extract from the register of entrepreneurs should contain information on the person(s) authorized to represent the Marketing Authorisation Holder. If the Marketing Authorisation Holder acts through commercial attorney, such attorney must be named in the register.

For companies registered in Poland, an extract from the register of entrepreneurs of the National Court Register should be submitted.

For companies registered in other EU/EEA Member States, an extract from the relevant register of entrepreneurs of a given country should be submitted.

If the person authorized to represent the Marketing Authorisation Holder does not appear in the register of entrepreneurs, another proof of such authorisation must be provided – original document in Polish or original document in other language along with a translation into Polish.

2. **The form and format of the extract from the register of entrepreneurs**

The document must originate from the official register of entrepreneurs of EU/EEA Member State.

The following official documents shall be accepted:

- officially certified documents (originals)
- copies of hard-copy documents (issued in paper form)
- copies and printouts from electronic registers of entrepreneurs.

3. Document should be drawn up in Polish

If the extract from the register of entrepreneurs 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.

4. Document should be up-to-date

If the Marketing Authorisation Holder is represented by a person or persons indicated in the register of entrepreneurs, the extract from the register of entrepreneurs should contain information valid as at the date of submitting the application.

If the Marketing Authorisation Holder acts through an attorney, the extract from the register of entrepreneurs should contain information valid as of the date of granting the power of attorney (the extract from the register of entrepreneurs should indicate the person who is or was authorised to sign the power of attorney).

<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 authorisations for medicinal products for human use
- 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 should be made in Polish or English. If the extract from the register of entrepreneurs is not in Polish or English, it must be accompanied by a translation into Polish or English. The translation should be certified by a sworn translator.
2) An extract from the register of entrepreneurs supporting a variation application should be submitted according to footnote 6 eAF (electronic application form).

History of changes:
1.0 – 08.04.2021 – first version
1.1 – 01.03.2024 – change in point 3 (unification of the requirements to present an extract from the relevant register of entrepreneur in Polish); editorial changes
1.2 – 14.02.2025 – update of the name of regulation 1234/2008