

<p>REGULATION ON THE CONTENT OF MARKETING AUTHORISATIONS FOR MEDICINAL PRODUCTS (<i>Official Gazette of the RS</i>, No. 93/2005)</p>
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## I INTRODUCTORY PROVISION

### Article 1

This Regulation defines the content of marketing authorisations for medicinal products (hereinafter: authorisation) issued by the Serbian Agency for Medicinal Products and Medical Devices (hereinafter: the Agency).

## II CONTENT OF THE AUTHORISATION

### Article 2

The authorisation referred to in Article 1 of this Regulation contains the following:

- 1) data about the holder of the authorisation;
- 2) data about the manufacturer;
- 3) name of the medicinal product (proprietary name, INN or generic name);
- 4) pharmaceutical form, strength and packaging of the medicinal product;
- 5) qualitative and quantitative composition of the active substance of the medicinal product;
- 6) anatomical-therapeutic-chemical classification code for the medicinal product (ATC), or the anatomical-therapeutic-chemical veterinary classification for the medicinal product (ATC-vet);
- 7) the medicinal product classification (JKL) code;
- 8) the regime of dispensing the medicinal product, in accordance with the prescribed medicinal product classification;
- 9) information about the content of narcotic or psychotropic substances;
- 10) the number of the authorisation;
- 11) the EAN identification code of the medicinal product (13 or 8 digits);
- 12) the date of the authorisation;
- 13) signature of the responsible official of the Agency;
- 14) information about legal remedies.

### Article 3

The following are constituents of the authorisation referred to in Article 2 of this Regulation:

- 1) summary product characteristics with approved regime of dispensing the medicinal product;
- 2) patient information leaflet with approved regime of dispensing the medicinal product.

### Article 4

The authorisation referred to in Article 2 of this Regulation contains data about the term to which the authorisation is granted.

In the authorisation referred to in § 1 of this Article is specified whether the authorisation was issued for a period of five years or to a period of less than five years.

### Article 5

Authorisations are granted to periods of less than five years in the following cases:

- 1) for medicinal products used in experimental or insufficiently established therapy;
- 2) where the indications for the medicinal product specified in the documentation are so rare that it is not possible to provide other types of evidence about indications within a reasonable period of time;
- 3) where it is not possible to provide more extensive information about the medicinal product on account of current development of scientific knowledge;
- 4) where acquisition of other information and evidence about the medicinal product would contravene generally accepted principles of medical ethics.

#### Article 6

In authorisations granted for periods of less than five years may also be listed specific requirements relating to the obligation of the holder of the authorisation to conduct requisite studies of the medicinal product's safety and efficacy, as well as special monitoring of the undesirable reactions to the medicinal product, to be implemented subsequent to the issuance of the authorisation.

### III CONCLUDING PROVISION

#### Article 7

This Regulation shall enter into force on the eighth day from the date of its publication in the *Official Gazette of the Republic of Serbia*.