THE CROATIAN PARLIAMENT

1931

Pursuant to Article 89 of the Constitution of the Republic of Croatia, I hereby issue the

DECISION

PROMULGATING THE ACT ON

AMENDMENTS TO THE MEDICINAL PRODUCTS ACT

I hereby promulgate the Act on Amendments to the Medicinal Products Act, passed by the Croatian Parliament at its session on 31 October 2018.

Class: 011-01/18-01/130

Reg. No: 71-06-01/1-18-2

Zagreb, 5 November 2018

The President of the
Republic of Croatia
Kolinda Grabar-Kitarović, m.p.

ACT

ON AMENDMENTS TO THE MEDICINAL PRODUCTS ACT

Article 1

In the Medicinal Products Act (Official Gazette 76/13 and 90/14) in Article 6 paragraph 4 is deleted.

Article 2

In Article 92 paragraph 2 the words: »The Minister shall lay down in an ordinance« are replaced by the words: »The Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use shall regulate.«.

Article 3

In Article 118 paragraph 2 is deleted.

The former paragraphs 3 and 4 become paragraphs 2 and 3.

Article 4

In Article 129 paragraph 1 after subparagraph 3 a new subparagraph 4 is added which reads:

» – for clinical tests,«.

The former subparagraphs 4 to 6 become subparagraphs 5 to 7.

Article 5

Article 188 is amended to read:

»Prices of medicinal products that have, in conformity with the authorisation for marketing the medicinal product in the Republic of Croatia, been classified according to their dispensing method as medicinal products on prescription and which the marketing authorisation holder intends to place on the market in the Republic of Croatia, shall be set by the Agency in conformity with this Act.«.

Article 6

After Article 188, Article 188.a is added which reads:

»Article 188.a

(1) For the medicinal product referred to in Article 188 of this Act, that may be on the market in the Republic of Croatia pursuant to Article 22 paragraph 1 and Article 113 paragraph 1 of this Act, the Agency shall set the maximum permitted price of the medicinal product based on the application of the authorisation holder for marketing i.e. for wholesale distribution in case of parallel distribution.

(2) The authorisation holder for marketing i.e. for wholesale distribution shall have no obligation to submit an application to the Agency for setting the maximum permitted price of the medicinal product if the Agency has already set the maximum permitted price for the medicinal product under its common name.

(3) The marketing authorisation holder may submit to the Agency an application for an exceptional increase of the maximum permitted price of the medicinal product referred to in paragraph 1 of this Article.

(4) The application referred to in paragraph 3 of this Article shall be decided on by the Agency subject to a previously obtained approval from the Minister.

(5) The Minister shall grant or withhold the approval referred to in paragraph 4 of this Article in accordance with the need for optimum supply of medicinal products needed to implement health care for the population.

(6) The costs of calculation of the prices of medicinal products referred to in paragraph 1 of this Article, the prices of which are being determined for the first time, shall be set by the Agency subject to the prior approval of the Minister, and shall be borne by the applicant for the authorisation.

(7) The Agency shall carry out the procedure for annual calculation of prices of all the medicinal products referred to in paragraph 1 and 3 of this Article.

(8) On its website, the Agency shall regularly publish the list of medicinal products with the set maximum permitted price and the list of medicinal products with a price set exceptionally higher than the maximum permitted price of the medicinal product.

(9) The marketing authorisation holder i.e. the wholesale distribution authorisation holder shall not sell the medicinal product at a price greater than the maximum permitted price of the medicinal product referred to in paragraph 1 of this Article, that is, greater than the price exceptionally higher than the maximum permitted price of the medicinal product referred to in paragraph 4 of this Article.«.

Article 7

Article 189 is amended to read:

»(1) Based on the application referred to in Article 188.a paragraph 1 and 3 of this Act the Agency shall issue a decision within 30 days from the day of receipt of the orderly application.

(2) As part of the procedure referred to in paragraph 1 of this Article the Agency may request from the applicant that they submit additional supporting documents, in which case the deadline referred to in paragraph 1 of this Article shall be extended for an additional 15 days.

(3) The decision referred to in paragraph 1 of this Article cannot be appealed, but administrative proceedings may be instituted against it.

(4) Once a year the Agency shall submit to the European Commission a list of all medicinal products with a set maximum permitted price and of medicinal products with a price exceptionally higher than the maximum permitted price of the medicinal product.

(5) The Minister shall by virtue of an ordinance define in more detail the criteria for setting the maximum permitted price of the medicinal product for wholesale distribution and the price exceptionally higher than the maximum permitted price of the medicinal product for wholesale distribution and the criteria for annual calculation of the price of the medicinal product.«.

Article 8

Article 190 is amended to read:

»(1) The Institute may also set a price lower than the price of the medicinal product set in accordance with Article 188.a of this Act, as part of the procedure for including the medicinal product on the list of medicinal products of the Institute in accordance with the provision of Article 191 of this Act.

(2) The price of the medicinal product set in accordance with Article 188.a of this Act may also be lower based on a contractual relation with:

– contractual health institutions (contractual subjects of the Institute), as part of a public procurement procedure

– other natural and legal persons that have authorisation for performing healthcare activities

– the Ministry of Defence for the purpose of supporting health care of members of the armed forces or

– the Croatian Institute of Public Health.

(3) The marketing authorisation holders that are at the same time health institutions founded by the Republic of Croatia which produce medicinal products of national interest shall apply the criteria of cost-based pricing when setting the prices referred to in paragraph 1 and 2 of this Article.

(4) When setting the price of medicinal products in accordance with paragraph 3 of this Article the marketing authorisation holders shall obtain prior approval from the Minister.

(5) After obtaining prior approval from the Minister in accordance with paragraph 4 of this Article the marketing authorisation holders shall negotiate prices together with subjects referred to in paragraph 1 and 2 of this Article.«.

Article 9

Article 191 is amended to read:

»(1) The application for inclusion of a medicinal product on the Institute's list of medicinal products may be submitted by the marketing authorisation holder only for a medicinal product for which the Agency has previously set a maximum permitted price of the medicinal product in accordance with the provisions of this Act.

(2) In addition to the person referred to in paragraph 1 of this Article, the Institute's Committee for Medicinal Products, committees for medicinal products of various healthcare institutions and hospitals, expert groups of the Croatian Medical Association and other professional bodies and referral centres of the Ministry may also submit proposals for a change of status or amendment of a therapeutic indication or a change of prescription guidelines for a medicinal product that is already included in the Institute's list.

(3) The Institute's Committee for Medicinal Products and committees for medicinal products of various healthcare institutions and hospitals may propose the medicinal product to be added to the Institute's list of medicinal products under its common name if there is a justified need for its use.

(4) The Institute shall adopt a decision on the application referred to in paragraph 1 of this Article within 90 days from the day of receipt of an orderly application.

(5) The deadline for adoption of the decision of the Agency referred to in Article 189 paragraph 1 of this Act and the deadline for adoption of the decision of the Institute referred to in paragraph 4 of this Article may not exceed cumulatively 180 days.

(6) The decision referred to in paragraph 4 of this Article cannot be appealed, but administrative proceedings can be instituted against it.

(7) The criteria for inclusion of medicinal products in the Institute's list of medicinal products as well as the method for setting the price of medicinal products to be financed by the Institute and the method of reporting thereon shall be laid down by the Minister by an ordinance.«.

Article 10

After Article 191 a new Article 191.a is added which reads:

»Article 191.a

(1) The decision on the removal of medicinal products from the Institute's list of medicinal products, on the basis of a previously obtained opinion of the Institute's Committee for Medicinal Products, shall be taken by the Management Board of the Institute, at the request of the marketing authorisation holder.

(2) Based on the decision referred to in paragraph 1 of this Article the Institute shall adopt a decision on removal of a medicinal product from the Institute's list.

(3) If the medicinal product is removed from the Institute's list of medicinal products and there is a justified need for its further use, the medicinal product may remain on the Institute's list of medicinal products under its common name.

(4) The decision referred to in paragraph 2 of this Article may not be appealed, but administrative proceedings can be instituted against it.«.

Article 11

Article 192 is deleted.

Article 12

In Article 212 paragraph 1, after subparagraph 4 a new subparagraph 5 is added which reads:

» – set the maximum permitted price of the medicinal product, that is, the price exceptionally higher than the maximum permitted price of the medicinal product authorised for marketing in the Republic of Croatia referred to in Article 188.a paragraph 1, that is, Article 188.a paragraph 3 of this Act, and carry out the procedure for annual calculation of the price of medicinal products«.

The former subparagraphs 5 to 41 become subparagraphs 6 to 42.

Article 13

In Article 226 paragraph 1, item 31 is amended to read:

»31. if they sell a medicinal product at a price higher than the maximum permitted price, that is, at a price higher than the price that is exceptionally higher than the maximum permitted price of the medicinal product (Article 188.a paragraph 9)«.

Article 14

The ordinances referred to in Article 7 and 9 of this Act shall be issued by the Minister within three months from the day of entry into force of this Act.

Article 15

For medicinal products that have a marketing authorisation in the Republic of Croatia and have been, taking into account their method of dispensing, classified as prescription medicinal products, but have not been included on the Institute's lists of medicinal products and are already on the market in the Republic of Croatia on the day of entry into force of this Act, the prices set for these medicinal products at the time of their placement on the market before the day of entry into force of this Act shall apply until the Agency carries out the procedure of annual calculation of medicinal product prices in conformity with this Act.

Article 16

The prices calculated by the Institute in the annual calculation procedure carried out prior to the entry into force of this Act shall apply until the completion of the procedure for annual calculation of medicinal product prices in conformity with Article 188.a of this Act, which will be carried out after the entry into force of this Act.

Article 17

In the entire text of the Medicinal Products Act (Official Gazette 76/13 and 90/14) the words: »basic or supplementary reimbursement list of the Institute« in all case and number shall be replaced by the words: »Institute's list of medicinal products in accordance with the act regulating compulsory health insurance «, in appropriate case and number.

Article 18

Procedures initiated prior to the day of entry into force of this Act shall be completed pursuant to the provisions of the Medicinal Products Act (Official Gazette 76/13 and 90/14).

Article 19

This Act shall enter into force on the eighth day after the day of its publication in the Official Gazette.

Class: 022-03/18-01/99

Zagreb, 31 October 2018.

THE CROATIAN PARLIAMENT

The President of the
Croatian Parliament
Gordan Jandroković, m.p.