

BOSNA I HERCEGOVINA
Konkurencijsko vijeće



БОСНА И ХЕРЦЕГОВИНА
Конкуренијски савјет

CONCLUSION
on innitiation of proceedings

Sarajevo,
February 2012



Number: 04-26-3-027-7-II/11
Sarajevo, 14th February 2012

Pursuant to Article 25 and Article 32 paragraph (1) and (2) of the Competition Act ("Official Gazette of BiH", No. 48/05, 76/07 and 80/09) and Article 210 of the Law on administrative procedure ('Official gazette of BiH', No. 29/02, 44/02, 12/04, 88/07 and 93/09), following the Request on initiation of proceedings, No: 04-26-3-027-II/11 filed on 1st December 2011, by Association of representatives of international producers of medicaments in Bosnia and Herzegovina, Hasana Brkića 2, 71000 Sarajevo, represented by attorney Almir A. Selimović, Maršala Tita 29/II, 71000 Sarajevo, against Government of Federation of Bosnia and Herzegovina, Alipašina 41, 71000 Sarajevo, for prevention and distortion of competition in terms of Article 4 paragraph (1) item b) of the Competition Act, Council of Competition at its 28th (twenty-eighth) session held on 14th February 2012, has issued

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- 1) Procedure is instituted based on the Request for initiation of proceedings filed by the Association of representatives of international producers of medicaments in Bosnia and Herzegovina against the Government of the Federation of Bosnia and Herzegovina, in order to establish the existence of an agreement prohibited by Article 4 paragraph (1) item b) of the Competition Act.
- 2) The procedure shall be conducted in accordance with the Competition Act and the laws that regulate market competition and other relevant regulations.
- 3) The parties to the proceedings and other legal and natural persons are required to submit all requested documents and to fulfill other requirements of the Council of Competition within the meaning of Article 35 of the Competition Act, within the time specified by the Council of Competition, in accordance with Article 33 paragraphs (2), (3) and (4) of the same Act.

Exposition

Association of representatives of international producers of medicaments in Bosnia and Herzegovina (hereinafter: Association or Applicant), represented by attorney Almir A. Selimović, Maršala Tita 29/II, 71000 Sarajevo, has filed the Request for initiation of proceedings (hereinafter: Request), received on 1st December 2011 No. 04-26-3-027-II/11 (hereinafter: Request), for determination of compliance of the Decision on the list of essential medicaments necessary for insurance of health protection within the standard of obligatory health insurance in Federation of Bosnia and Herzegovina ("Official Gazette of FBiH" No 75/11) (hereinafter: Decision) with the Competition Act (hereinafter: Act).

After examining the submitted documents Council of Competition found that it was not full and complete, within the meaning of Article 28 paragraph (2) of the Act, and requested to supplement to the Request in document No. 04-26-3-027-1-II/11 of 7th December 2011.

The Applicant submitted the requested amendment, submissions received on 16th December 2011, number: 04-26-3-027-2-II/11 and on 22nd December 2011, number: 04-26-3-027-3-II/11.

Council of Competition, pursuant to Article 28 paragraph (3) has issued the Applicant a certificate of receipt of complete and adequate Request on 23rd January 2012, No. 04-26-3-027-4-II/11,

The Applicant has submitted on its own initiative Decision on the list of drugs required to provide health care within the standards of compulsory health insurance in Una Sana Canton No. 03-017-1117/2012 of 12th January 2012, on 02/02/2012, No. 04-26-3-027-6-II/11, since it considers it relevant to the present case.

In the Request for institution of proceedings Applicant essentially states the following:

- That the Association is registered in the Register of Associations of the Ministry of Justice of Bosnia and Herzegovina, on 05/31/2002, under the number RU-2/02, book of the I Register, based in Hasana Brkica 2, 71000 Sarajevo;

- That one of the objectives of the Association is to represent the interests of the Association, that may be affected by the Decision in question, or that individual members of the Association may be lead to question economic justification for continued existence in the market of Bosnia and Herzegovina;

- That the Government of the Federation of Bosnia and Herzegovina, in the provisions of paragraph V and VIII of the Decision, prevents and distorts market competition in the market for drugs that are issued at the expense of health insurance in the Cantons of the Federation of Bosnia and Herzegovina, and questions competence of the Government of the Federation of Bosnia and Herzegovina, having in mind that this is a regulation that is the prerogative of the Council of Ministers;

- That the point V of the Decision stipulates that the price of the drug, which is on the Federal essential list is calculated after the negotiated procedure with manufacturers who have licenses for drugs issued by the Agency for Medicines and Medical Devices of Bosnia and Herzegovina, and believes that this provision denied the right to individual drug manufacturers to participate in the creation of drug prices, which are determined for certain drug in larger amount compared to the prices that were up to the Decision and that as evidence that they have not participated in the negotiation process, presented two letters of undertaking" Alcon Pharmaceuticals BH " d.o.o. Sarajevo, dated 9th December 2011, directed to the Federal Ministry of Health and undertaking NOBEL ILAC mission in Bosnia and Herzegovina, Sarajevo, dated 24th November 2011, addressed to the Association;

- Section VIII of the Decision sets out the general and specific criteria when making the positive list of Canton, including specific criteria and the restriction criteria that the positive list may include a maximum of five (5) drug trade names within the same generic name, form, strength and packaging;

- That the criterion which must be included on the list of domestic pharmaceutical industry if they have registered a generic counterpart of the same drug, packaging and strength in the case of five domestic producers of medicines that meet the specified conditions can lead to the absolute exclusion of foreign drug manufacturers from competition.

- That this case has already been the subject of discussion of the Council of Competition, upon the request of the Association against the Government of Canton Sarajevo, in which the Council of Competition adopted Resolution No. 01-01-26-048-36-II/07 of 22nd October 2008, which provides that the provision of Article 20 of the Decision on the list of drugs that are issued on the burden of the Health Insurance Institute of Sarajevo Canton, in accordance with the provisions of Article 4 (1) of the Act;

Based on the above, the Applicant considers that the Decision of the Government of the Federation of Bosnia and Herzegovina, items V and VIII restrict competition and prevent market (opening up the possibility of abuse and privileges for some manufacturers), pursuant to Article 4 paragraph (1) item b) of the Act.

Also, Applicant, proposes that the Council of Competition while pending a final decision issues a decision on temporary suspension of implementation of Decision made within the meaning of Article 40 (2) of the Act, which would suspend implementation of the Decision, with the aim of protection and promotion of market competition in Bosnia and Herzegovina and the prevention of harmful consequences, both for the individual undertakings, and for the community in general.

Consequently, the Competition Council found that it is not possible to determine violations of the Act, the Applicant indicates to, without conducting the proceedings, and has decided as outlined in this Conclusion.

After the procedure Council of Competition shall make a final decision in accordance with Article 42 of the Act within the Article 41 of the same Act.

Legal remedies

No appeal is allowed against this Conclusion.

President

Ibrica Lakišić