

BOSNA I HERCEGOVINA
Konkurencijsko vijeće



БОСНА И ХЕРЦЕГОВИНА
Конкуренијски савјет

DECISION
on the Request for the extension of the individual agreement exemption from the prohibition of
the undertakings Stada Arzneimittel AG, Republic of Germany and Opella Healthcare
International SAS, Republic of France

"Abridged Version"

Sarajevo
June, 2026



Number: UP 03-26-4-006-28/25
Sarajevo, 12 June 2026

Pursuant to the Article 25 and Article 42, and in accordance with Article 6, paragraph (3) of the Law on Competition ("Official Gazette of Bosnia and Herzegovina", number 48/05, 76/07 and 80/09), in the proceeding at the request for the extension of the deadline for the individual exemption of the agreement from prohibition, received on 28.11.2025., under number: UP 03-26-4-06-11/25, undertakings Stada Arzneimittel AG, Stadastraße 2-18 61118 Bad Vilbel, Republic of Germany and Opella Healthcare International SAS, 157 Avenue Charles de Gaulle, Neuilly sur Seine, 92200, France, represented by lawyers Nihad Sijerčić, Amina Đugum Brkanić, Jasmin Omerdić and Lejla Bošnjak, Trg djece Sarajeva 1, ARIA Centar, 71 000 Sarajevo, Competition Council at the 45th (forty-fifth) session held on 12.6.2026., issued the following

DECISION

1. The extension of the term of the individual exemption of the agreement from the prohibition, which refers to the Exclusive Distribution Agreement concluded between the undertakings Stada Arzneimittel AG and Opella Healthcare International SAS, in the sense of Article 6, paragraph (3) of the Law on Competition, is determined to be allowed.
2. The individual exemption from point (1) of the enacting clause of this Decision is established for a period of two years starting from 23.7.2026.
3. Undertakings Stada Arzneimittel AG and Opella Healthcare International SAS are obliged to pay an administrative fee in the total amount of 1,000.00 KM in favor of the Budget of the institutions of Bosnia and Herzegovina.
4. This Decision is final and will be published in the Official Gazette of Bosnia and Herzegovina, the official gazettes of the entities and the Brčko District of Bosnia and Herzegovina.

Exposition

On 19 February 2025, under the number: UP 04-26-4-06-1/25, the Competition Council received the Request for individual exemption of the agreement from the prohibition (hereinafter: Request) of undertakings Stada Arzneimittel AG, Stadastraße 2-18 61118 Bad Vilbel, Republic of Germany (hereinafter: STADA) and Opella Healthcare International SAS, 157 Avenue Charles de Gaulle, Neuilly sur Seine, 92200, France (hereinafter: OPELLA) (hereinafter jointly for STADA and OPELLA: Applicants or Parties), in the sense of Article 4 and 5 of the Law on Competition ("Official Gazette of BiH", no. 48/05, 76/07 and 80/09), (hereinafter: Law).

After analyzing the Request, the Competition Council determined that Decision No.: UP 02-26-4-40-15/21 dated 24.11.2021. already exempted from the prohibition the restrictive provisions from the Existing Contract for a period of five years until 22.7.2026., and which are unchanged in the Agreement on Exclusive Distribution dated 04.12.2024., and that the contracting parties can only submit a request for the extension of the individual exemption of the agreement from the prohibition in the sense of Article 6, paragraph (3) of the Law on Competition. In this regard, on 11.06.2025. by document number: UP 03-26-4-006-6/25, the Applicants were asked to edit the request, that is, to

submit a request for the extension of the individual exemption agreement from the prohibition in the sense of Article 6, paragraph (3) of the Law on Competition.

On 28.11.2025., the Competition Council received the Request for the extension of the individual exemption number: UP 03-26-4-006-11/25.

In accordance with Article 6, paragraph (4) of the Law, the party submitted the Request for the extension of the validity period of the individual exemption to the Competition Council no later than four months before the expiry date. The request for the extension of the individual exemption deadline was submitted on 28 November 2025., and as a result of the aforementioned, the relevant request for individual exemption was submitted in a timely manner.

The Competition Council determined that the request is complete and orderly in the sense of Article 29, paragraph (1) of the Law, and based on Article 29, paragraph (3) of the Law on 23.3.2026. issued a Confirmation of receipt of a complete and orderly Request, number: UP 03-26-4-006-13/25.

The Competition Council assessed that the extension of the individual exemption agreement from the prohibition cannot be determined without the implementation of the proceeding, and on 24.3.2026., issued a Conclusion on the initiation of the proceeding number: UP 03-26-4-006-15/25.

1. Parties to the proceedings

The parties to the proceedings are the undertakings Stada Arzneimittel AG, Stadastraße 2-18 61118 Bad Vilbel, Republic of Germany and Opella Healthcare International SAS, 157 Avenue Charles de Gaulle, Neuilly sur Seine, 92200, France.

2. The legal basis of the proceedings in question – Agreement on exclusive distribution

The legal basis of the proceeding is the Agreement on Exclusive Distribution (hereinafter: Agreement) concluded on 4 December 2024 between STADA Arzneimittel AG and Opella Healthcare International SAS.

3. The relevant market and the structure of the relevant market

In order to determine whether the conditions for an individual exemption were met, the Competition Council determined the relevant product/service market and the relevant geographic market in accordance with Article 3 of the Law and the provisions of the Regulation on relevant market during the evaluation of the contract in question.

The relevant market, in the sense of Article 3 of the Law, and Art. 4. and 5. of the Regulation on the relevant market, constitutes the market of certain products/services that are the subject of activities in a certain geographic market.

According to the provisions of Article 4 of the Regulation on relevant market, the relevant product market includes all products and/or services that consumers and/or users consider mutually interchangeable, under acceptable conditions, bearing in mind especially their essential features, quality, usual purpose, method of use, terms of sale and prices.

Taking into account the nature of the specific products included in the contract and the subject of the contract itself, as well as the fact that the exempted products distributed in Bosnia and Herzegovina (Buscopan, Dulcolax and Bisolvon) belong to ATC 3 classes (according to anatomical-therapeutic-chemical classification), the Competition Council has determined the relevant market to be the wholesale market of finished pharmaceutical products within ATC 3 classes A03B, A06A, and R05C.

Furthermore, according to Article 5 of the Decision on the relevant market, the relevant market in the geographical sense includes the entire or a significant part of the territory of Bosnia and Herzegovina where the undertaking operates in the sale and/or purchase of the relevant product under equal or sufficiently uniform conditions and which significantly differentiates that market from the conditions of market competition in neighboring geographic markets.

Given that the Agreement refers to the entire territory of Bosnia and Herzegovina, the Competition Council has determined the territory of Bosnia and Herzegovina as the relevant geographic market in the proceedings in question.

In accordance with the above, the Competition Council determined that the relevant market of the procedure in question is the wholesale of finished pharmaceutical products within ATC 3 classes A03B, A06A, and R05C on the territory of Bosnia and Herzegovina.

The Competition Council, for the purpose of conducting the proceedings in question, and with the aim of determining the structure of the wholesale market of finished pharmaceutical products within ATC 3 classes A03B, A06A, and R05C on the territory of Bosnia and Herzegovina, requested from the Agency for Medicines and Medical Devices of Bosnia and Herzegovina, data on undertakings that import, distribute and/or engage in the wholesale trade of medicines of anatomic-therapeutic-chemical classification (ATC 3) class A03B, class A06A and class R05C, for the period of 2023, 2024 and 2025 on the territory of Bosnia and Herzegovina.

In accordance with the request of the Competition Council, the Agency for Medicines and Medical Devices of Bosnia and Herzegovina, by act received under number UP 03-26-4-006-25/25 dated 25 May 2026 submitted the data on medicines from foreign manufacturers that were imported into Bosnia and Herzegovina and on medicines from domestic manufacturers that were produced and put on the market in Bosnia and Herzegovina. The Agency for Medicines and Medical Devices of Bosnia and Herzegovina submitted the requested data for 2023 and 2024, and the report for 2025 was not submitted for the reason that it is being prepared in the middle of the year for the previous year.

The contract on exclusive distribution concluded between the undertakings Stada Arzneimittel AG and Opella Healthcare International SAS, which is exempted from the prohibition by Decision on individual exemption number: UP 02-26-4-40-12/21 on the wholesale market of finished pharmaceutical products within ATC 3 classes A03B, A06A, and R05C in Bosnia and Herzegovina, applies from 2021. In this regard, the Competition Council, by act number: UP 03-26-4-006-21/25, requested the applicants to submit data on undertakings in Bosnia and Herzegovina that sold and distributed medicines defined by the contract in question, as well as data on undertakings with which the largest turnover was achieved.

At the request of the Competition Council, the applicants (undertaking Hemofarm d.o.o. Banja Luka) on 14 May 2026, (submission number: UP 03-26-4-006-22/25), provided data on undertakings in Bosnia and Herzegovina to which medicines were sold and distributed, during the duration of the individual exemption, as follows: Vega Pharmaceutical Logistics d.o.o., Hercegovinalijek Mostar, Interpromet d.o.o., Zefarm d.o.o., Medimpex d.o.o., Farmacija 2011 d.o.o. and Intel-Med d.o.o..

4. Relevant facts of the subject procedure and assessment

The Competition Council, by Decision number: UP 02-26-4-40-12/21, allowed the individual exemption of the agreement from the prohibition related to the Agreement on Exclusive Distribution concluded on 22 June 2021, between the undertakings Stada Arzneimittel AG, and Opella Healthcare International SAS, in the sense of Article 4, paragraph (3) and Article 5 of the Law on Competition.

According to the Decision of the Competition Council number: UP 02-26-4-40-12/21, the individual exemption was approved for a period of five years starting from 22 July 2021.

On 4 December 2024, undertakings STADA Arzneimittel AG and Opella Healthcare International SAS concluded a new Agreement on exclusive distribution, in which the restrictive provisions that are the subject of individual exemption from the Decision on Individual Exemption of the Agreement from the prohibition number: UP 02-26-4-40-15/21 of 24 November 2021, remained the same. In this regard, on 28 November 2025, the undertakings STADA Arzneimittel AG and Opella Healthcare International SAS submitted a request for an extension of the deadline for an individual exemption in the sense of the provisions of Article 6, paragraph (3) of the Law.

In the Request, supplement to the request and submissions submitted at the request of the Competition Council, the main reasons for the extension of the individual exemption are stated, as follows:

Description and detailed explanation of the economic benefits that are a direct consequence of the agreement

(...)

Description and detailed explanation of the expected benefits that will arise from the implementation of the agreement from the point of view of the consumer's interests

(...)

A detailed explanation of the necessity of the limiting effect of the agreement, that is, of each individual limitation from the agreement

(...)

Detailed explanation of the degree of restriction of competition on the relevant market due to the existence of the agreement

(...)

By evaluating the submitted Request requesting the extension of the individual exemption from the prohibition based on Article 6, paragraph (3) of the Law, the Competition Council as in the previously conducted procedure, determined that the Agreement on Exclusive Distribution meets the requirements of Article 4, paragraph (3) of the Law.

In accordance with Article 4, paragraph (1) of the Law, agreements, contracts, certain provisions of agreements or contracts, joint actions, express and tacit agreements of undertakings, as well as decisions and other acts of undertakings that have as their goal and effect the prevention, limitation or distortion of market competition on the relevant market, and which relate to the direct or indirect determination of purchase and sale prices or any other trading conditions, limitation and control of production, market, technical development or investment, are prohibited including the division of the market or source of supply, the application of different conditions for identical transactions with other undertakings, putting them in a disadvantageous position in relation to the competition, the conclusion of such agreements by which the other party is conditioned to accept additional obligations which by their nature or customs in trade are not related to the subject of the agreement.

In terms of Article 4, paragraph (3) of the Law, the agreements in question are not prohibited if they contribute to the improvement of the production or distribution of goods and/or services within Bosnia and Herzegovina, or to the promotion of economic development and technical development, whereby they allow consumers a fair share of the benefits arising from them, and which impose only the restrictions necessary to achieve the goals and do not enable the exclusion of competition in a significant part of the products or services in question.

In accordance with Article 5, paragraph (1) of the Law, the Competition Council, at the request of one or more parties to an agreement/contract, may issue a decision on individual exemption from the prohibition of agreements, from Article 4, paragraph (1) of the Law, if the agreement/contract meets the conditions, from Article 4, paragraph (3) of the Law.

According to Article 6, paragraph 2) and 3) of the Law, the individual exemption has a limited validity period, it cannot last longer than five years, but the validity period of the individual exemption can be extended by a maximum of five years at the request of the parties, if it is proven that the agreement still meets the conditions from Article 4, paragraph (3) of the Law.

Based on all the submitted evidence, the Competition Council assessed that, although the Agreement in question contains provisions related to the prohibited agreement from Article 4, paragraph (1) of the Law, the Applicant has sufficiently argued and proved the fulfillment of the conditions prescribed by the Law for the extension of the deadline for the individual exemption of the restrictive Agreement in question from the prohibition, since it still meets the conditions from Article 4, paragraph (3) of the Law, because the conclusion and implementation of the Agreement imposes only restrictions necessary to achieve the goals and not exclude competition in a significant part of the products and/or services in question, and consequently the Competition Council decided as in point 1 of this Decision.

Since no new circumstances have arisen that would significantly deviate from the facts established in the previously conducted procedure, the Competition Council, in accordance with Article 6, paragraph (3) of the Law, decided to approve the extension of the individual exemption within the time limit as in point 2 of this Decision.

5. Administrative fee

The Applicant for this Decision, in accordance with the provision of Article 2, paragraph (1) tariff number 107, point b) of the Decision on the amount of administrative fees in connection with procedural actions before the Competition Council ("Official Gazette of BiH", no. 30/06, 18/11 and 75/18), is obliged to pay an administrative fee in the amount of KM 1,000.00 in favor of the Budget of the institutions of Bosnia and Herzegovina.

6. Legal remedy

No appeal is allowed against this Decision.

An unsatisfied party may initiate an administrative dispute before the Court of Bosnia and Herzegovina within 30 days from the date of receipt, i.e. publication of this Decision.

President

Ninela Salihbašić