The Constitutional Court of Bosnia and Herzegovina, sitting, in accordance with Article VI (3) (a) of the Constitution of Bosnia and Herzegovina, Article 57 (2) (b), Article 59 (1) and (2) and Article 61 (2) and (3) of the Rules of the Constitutional Court of Bosnia and Herzegovina – Revised text (*Official Gazette of Bosnia and Herzegovina,* 94/14), in plenary and composed of the following judges:

Ms. Valerija Galić, President
Mr. Mirsad Ćeman, Vice-President
Mr. Zlatko M. Knežević, Vice-President
Ms. Helen Keller, Vice-President
Ms. Seada Palavrić,
Ms. Angelika Nussberger, and
Mr. Ledi Bianku

Having deliberated on the request filed by Mr. **Šefik Džaferović, Chairman of the Presidency of Bosnia and Herzegovina at the time of filing the request,** in the case no. **U-17/22,** at its session held on 1 and 2 December 2022, adopted the following

DECISION ON ADMISSIBILITY AND MERITS

Deciding on the request of Mr. **Šefik Džaferović, Chairman of the Presidency of Bosnia and Herzegovina at the time of filing the request**, for review of the constitutionality of the Law on Pharmaceuticals and Medical Devices of the Republika Srpska (*Official Gazette of the Republika Srpska*, 118/21) and the Law on Amendments to the Law on the Republic Administration (*Official Gazette of the Republika Srpska*, 15/22),

it is hereby established that the Law on Pharmaceuticals and Medical Devices of the Republika Srpska (*Official Gazette of the Republika Srpska*, 118/21) and the Law on Amendments to the Law on the Republic Administration (*Official Gazette of the Republika Srpska*, 15/22) are not in conformity with Articles I (2) and III (3) (b) of the Constitution of Bosnia and Herzegovina.

Pursuant to Article 61 (2) of the Rules of the Constitutional Court of Bosnia and Herzegovina, the Law on Pharmaceuticals and Medical Devices of the Republika Srpska (*Official Gazette of the Republika Srpska*, 118/21) and the Law on Amendments to the Law on the Republic Administration (*Official Gazette of the Republika Srpska*, 15/22) shall be repealed.

Pursuant to Article 61 (3) of the Rules of the Constitutional Court of Bosnia and Herzegovina, the repealed Law on Pharmaceuticals and Medical Devices of the Republika Srpska (*Official Gazette of the Republika Srpska*, 118/21) and Law on Amendments to the Law on the Republic Administration (*Official Gazette of the Republika Srpska*, 15/22) shall be rendered ineffective

on the first day following the date of the publication of this decision of the Constitutional Court in the *Official Gazette of Bosnia and Herzegovina*.

This Decision shall be published in the *Official Gazette of Bosnia and Herzegovina*, the *Official Gazette of the Federation of Bosnia and Herzegovina*, the *Official Gazette of the Republika Srpska* and in the *Official Gazette of the Brčko District of Bosnia and Herzegovina*.

REASONING

I. Introduction

1. On 28 June 2022, Mr. Šefik Džaferović, the Chairman of the Presidency of Bosnia and Herzegovina at the time of filing the request ("the applicant"), submitted a request to the Constitutional Court of Bosnia and Herzegovina ("the Constitutional Court") for review of the constitutionality of the Law on Pharmaceuticals and Medical Devices of the Republika Srpska (*Official Gazette of the Republika Srpska*, 118/21; "the RS Law on Pharmaceuticals") and the Law on Amendments to the Law on Republic Administration (*Official Gazette of the Republika Srpska*, 15/22; "the Law on Amendments to the Law on RA").

2. In addition, based on Article 64 of the Rules of the Constitutional Court, the applicant filed a request for adoption of an interim measure, by which the Constitutional Court would temporarily render ineffective the RS Law on Pharmaceuticals and the Law on Amendments to the Law on RA, pending a final decision of the Constitutional Court.

II. Procedure before the Constitutional Court

3. The Constitutional Court adopted Decision on interim measure no. *U-17/22* of 6 July 2022, granting the applicant's request and rendering the RS Law on Pharmaceuticals and the Law on Amendments to the Law on RA temporarily ineffective.

4. Pursuant to Article 23 (2) of the Rules of the Constitutional Court, on 1 July 2022, the National Assembly of the Republika Srpska ("the National Assembly") was requested to submit its reply to the request within 30 days from the day of receiving the letter.

5. On 26 July 2022, the National Assembly requested the extension of the deadline for submission of the reply to the request. The Constitutional Court extended the deadline to 1 September 2022, pursuant to Article 23 (1) of the Rules of the Constitutional Court.

6. On 1 September 2022, the National Assembly submitted the reply to the request.

III. Request

I. Allegations stated in the request

7. The applicant contends that the RS Law on Pharmaceuticals and the Law on Amendments to the Law on RA are in contravention of the provisions of Article I (2), Article I (4), Article II (4), Article III (3) (b) and Article III (5) (a) of the Constitution of Bosnia and Herzegovina.

8. In support of his allegations, the applicant states that the National Assembly, contrary to the provisions of the Constitution of Bosnia and Herzegovina and the laws of Bosnia and Herzegovina, as decisions of the institutions of Bosnia and Herzegovina, passed the challenged Laws which are contrary to the principle of the rule of law referred to in Article I (2) of the Constitution of Bosnia and Herzegovina, and the provisions of Article III (3) (b) of the Constitution of Bosnia and Herzegovina. In that regard, the applicant indicates that the Law on Pharmaceuticals and Medical Devices of Bosnia and Herzegovina ("the Law on Pharmaceuticals of BiH"), which established the institutional and legal framework in the field of medicines and medical devices in Bosnia and Herzegovina, was enacted pursuant to Article IV (4) (a) of the Constitution of Bosnia and Herzegovina. The Law on Pharmaceuticals of BiH established the Agency for Pharmaceuticals and Medical Devices of Bosnia and Herzegovina ("the BiH Agency"), as a single regulatory body at the level of Bosnia and Herzegovina in this field. In addition, the Control Laboratory of the BiH Agency and the Main Office for Pharmacovigilance were formed, bylaws were adopted, and the entire system was established, according to which these institutions exercise relevant duties, with a view to protecting and promoting health by providing quality, safe and effective medications. In view of the aforementioned, the applicant considers that it is undoubtedly the competence of Bosnia and Herzegovina, which can neither be transferred nor restored to the Entities and, therefore, the decision itself cannot generate any legal consequences in that regard.

9. In the applicant's opinion, the Entity of the Republika Srpska does not have any jurisdiction when it comes to the field of medicines and medical devices. Therefore, the applicant considered that the RS Law on Pharmaceuticals constituted a "direct attack on the Constitution of Bosnia and Herzegovina". Namely, the applicant states that such a regulation cannot exist in parallel with the Law on Pharmaceuticals of BiH, due to both formal impossibility for an Entity to pass such a piece

of legislation and reasons concerning practical aspects of its application, particularly so in the field which should be within the responsibility of the Agency for Pharmaceuticals and Medical Devices of the Republika Srpska ("the RS Agency"). In addition, the applicant indicated that the Law on Amendments to the Law on RA is in contravention of the Constitution of Bosnia and Herzegovina, for it has taken over the competence of the State. In fact, it enabled the establishment of an unconstitutional Entity Agency, which was assigned the competencies in the field already covered by the BiH Agency.

10. In addition to the aforementioned, the applicant stated that the National Assembly did not have a legal basis for the enactment of the challenged laws, as well as that the contents thereof was also disputable. In that regard, on pages 16 through 22 of the request, the applicant presented in detail the comparison of the contents of the provisions of the Law on Pharmaceuticals of BiH with the RS Law on Pharmaceuticals and the Law on Amendments to the Law on RA. The applicant emphasised that it followed therefrom that the challenged Laws had the purpose of establishing a separate market of the Republika Srpska, which is possible to observe already from the provision of Article 1 of the RS Law on Pharmaceuticals. This is to say, as further reasoned by the applicant, that the challenged laws had an objective to "particularly regulate the field of pharmaceuticals and medical devices" solely for the Republika Srpska. According to the opinion of the applicant, the establishment of special regulations for the treatment of same goods and the trade thereof, jeopardizes legal certainty as well as compromises already established system at the State level.

11. Further, the applicant stated that the National Assembly passed the challenged laws contrary to the provisions of the laws already passed by the Parliamentary Assembly of Bosnia and Herzegovina ("the Parliamentary Assembly"), thereby violating the provision of Article IV (4) of the Constitution of Bosnia and Herzegovina. Finally, the applicant deems that, by passing the challenged Laws, the National Assembly also violated the provision of Article III (5) (a) of the Constitution of Bosnia and Herzegovina, as it thereby entered the scope of responsibilities previously assumed by Bosnia and Herzegovina.

II. Reply to the request

12. The National Assembly deems that the applicant's allegations are completely unfounded insofar as they suggest that the RS Law on Pharmaceuticals and the Law on Amendments to the Law on RA are in contravention of the Constitution of BiH, in terms of both formal and substantive law.

13. In the reasoning for the reply to the request, the National Assembly states that the constitutional basis for the enactment of the RS Law on Pharmaceuticals is contained in Article 68 of the Constitution of the Republika Srpska, according to which the Republika Srpska regulates and provides healthcare. In addition, it states that Article 37 of the RS Constitution stipulates that everyone shall be entitled to health care and that the right to health care shall be guaranteed in conformity with law. Next, the National Assembly indicates that the challenged law renders ineffective the formerly applicable RS Law on Pharmaceuticals (Official Gazette of the Republika Srpska, 19/01, 113/05 and 34/08). In view of the aforementioned, the National Assembly states that the allegation made in the request that the law was passed without a valid Entity's constitutional basis is ill-founded. In that respect, the National Assembly indicates that also the Federation of Bosnia and Herzegovina had passed in 2012 the Law on Pharmaceuticals (*Official Gazette of FBiH*, 109/2012), but the applicant did not challenge the constitutionality of that law, therefore "a question arises as to the essential motive behind the applicant's request".

14. Furthermore, the National Assembly states that the applicant's conclusion that the Parliamentary Assembly had the responsibility for passing the Law on Pharmaceuticals of BiH and for founding the BiH Agency was wrong. In that respect, the National Assembly deems as ill-founded the applicant's position that this group of additional responsibilities did not require the consent and agreement by the Entity, but that they concerned the areas, which Bosnia and Herzegovina may and has to regulate unilaterally. Namely, the National Assembly states that everything not prescribed as the responsibility of the State shall be considered the responsibility of the Entities. Accordingly, the presumption of responsibility lies on the Entities. On the other hand, the State has to prove at all times that the Constitution of BiH has assigned a certain responsibility to the State, and if it fails to do so or if there is a doubt about it, the National Assembly deems that the responsibility in question belongs to the Entities.

15. As to the contents of the RS Law on Pharmaceuticals, the National Assembly indicates that Article 136 of the said Law prescribes the recognition of licenses issued by the BiH Agency and the Ministry of Foreign Trade and Economic Relations of Bosnia and Herzegovina. The establishment of the RS Agency, as further suggested, is not aimed at compromising or disrupting the work of another regulatory body of Bosnia and Herzegovina. The RS Agency is established "exclusively for the protection and welfare of the public health of the inhabitants of the Republika Srpska", which was jeopardised through inadequate conduct on the part of the competent bodies in the area of pharmaceuticals and medical devices at the level of Bosnia and Herzegovina. In that regard, the National Assembly indicates that the BiH Agency was established after over a year since the

passing of the Law on Pharmaceuticals of BiH by relying on the work of the Agency for Pharmaceuticals of the Republika Srpska, which has been in existence until then. In view of the aforementioned, it is of the opinion that the allegations that the Republika Srpska adopts *ad hoc* solutions leading to compromising the quality of medicines in the market are ill-founded. The National Assembly deems that bylaws, which stipulate the establishment of a control laboratory, pharmacovigilance, materiovigilance, medicines sale and such like, were not adopted and the procedure for the adoption thereof was not the subject matter of the challenged laws, while the contents of the request deal with the said areas for the most part.

16. As to the allegations about unconstitutionality of the Law on Amendments to the Law on RA, the National Assembly indicates that the said allegations are also ill-founded in their entirety. Namely, given that the RS Law on Pharmaceuticals stipulated the founding of the Agency, and that the said Law entered into force, it was necessary to harmonise the Law on RA with the said regulation. The constitutional basis for passing amendments to the challenged law, according to the provision of the National Assembly, arises from Article 68, Article 70, paragraph 1, subparagraph 2 and Article 97 of the RS Constitution. In addition, the Law on Amendments to the Law on RA was passed by upholding the provisions of the Constitution of BiH, bearing in mind that Article III of the Constitution of BiH prescribes the responsibilities of and relations between the institutions of Bosnia and Herzegovina and those of the Entities. The said provision prescribes the issues which fall within the responsibilities of the institutions of Bosnia and Herzegovina, whereas Article III (3) (a) of the Constitution of BiH prescribes that all governmental functions and powers not expressly assigned in this Constitution to the institutions of Bosnia and Herzegovina shall be those of the Entities. Given that the areas of medicines and medical devices are not within the responsibility of the institutions of Bosnia and Herzegovina, the National Assembly considers ill-founded the allegations of the applicant suggesting that a violation of the provisions of the Constitution of BiH occurred.

IV. Relevant Laws

17. The **Constitution of Bosnia and Herzegovina,** as relevant, reads:

Article I(2)

2. Democratic Principles

Bosnia and Herzegovina shall be a democratic state, which shall operate under the rule of law and with free and democratic elections.

Article III (1), (3) and (5)

Responsibilities of and Relations between the Institutions of Bosnia and Herzegovina and the Entities

1. Responsibilities of the Institutions of Bosnia and Herzegovina

The following matters are the responsibility of the institutions of Bosnia and Herzegovina:

a) Foreign policy.

b) Foreign trade policy.

c) Customs policy.

d) Monetary policy as provided in Article VII.

e) Finances of the institutions and for the international obligations of Bosnia and Herzegovina.

f) Immigration, refugee, and asylum policy and regulation.

g) International and inter-Entity criminal law enforcement, including relations with Interpol.

h) Establishment and operation of common and international communications facilities.

i) Regulation of inter-Entity transportation.

j) Air traffic control.

3. Law and Responsibilities of the Entities and the Institutions

a) All governmental functions and powers not expressly assigned in this Constitution to the institutions of Bosnia and Herzegovina shall be those of the Entities.

b) The Entities and any subdivisions thereof shall comply fully with this Constitution, which supersedes inconsistent provisions of the law of Bosnia and Herzegovina and of the constitutions and law of the Entities, and with the decisions of the institutions of Bosnia and Herzegovina. The general principles of international law shall be an integral part of the law of Bosnia and Herzegovina and the Entities.

5. Additional Responsibilities

a) Bosnia and Herzegovina shall assume responsibility for such other matters as are agreed by the Entities; are provided for in Annexes 5 through 8 to the General Framework Agreement; or are necessary to preserve the sovereignty, territorial integrity, political

independence, and international personality of Bosnia and Herzegovina, in accordance with the division of responsibilities between the institutions of Bosnia and Herzegovina. Additional institutions may be established as necessary to carry out such responsibilities.

b) Within six months of the entry into force of this Constitution, the Entities shall begin negotiations with a view to including in the responsibilities of the institutions of Bosnia and Herzegovina other matters, including utilization of energy resources and cooperative economic projects.

Article IV (4), subparagraphs a) and e)

Parliamentary Assembly

4. Powers

The Parliamentary Assembly shall have responsibility for:

a) Enacting legislation as necessary to implement decisions of the Presidency or to carry out the responsibilities of the Assembly under this Constitution.

e) Such other matters as are necessary to carry out its duties or as are assigned to it by mutual agreement of the Entities.

18. The **Law on Pharmaceuticals and Medical Devices** (*Official Gazette of Bosnia and Herzegovina*, 58/08), as relevant, reads:

Pursuant to Article IV(4)(a) of the Constitution of Bosnia and Herzegovina, the Parliamentary Assembly of Bosnia and Herzegovina, at the 29th session of the House of Representatives, held on 14 May and 4 June 2008, and at the 18th session of the House of Peoples, held on 17 June 2008, passed the following

LAW ON PHARMACEUTICALS AND MEDICAL DEVICES

CHAPTER I. GENERAL PROVISIONS

Article 1

(Subject matter of the Law)

(1) Law on Pharmaceuticals and Medical Devices ("the Law") shall regulate: definition of pharmaceuticals and medical devices for use in human medicine; production, testing and marketing of pharmaceuticals and medical devices, conditions and measures for ensuring quality, safety and efficacy of

pharmaceuticals and medical devices, supervision over pharmaceuticals and medical devices, as well as over legal entities engaged in production, testing or wholesale marketing of pharmaceuticals and medical devices; and any other issues of importance in the area of pharmaceuticals and medical devices.

(2) This Law applies also to pharmaceuticals containing narcotic drugs and psychotropic substances as well as raw materials used for their production, unless it has been regulated by a separate Law, in compliance with international conventions regulating this type of pharmaceuticals.

(3) This Law shall establish an Agency for Pharmaceuticals and Medical Devices of Bosnia and Herzegovina ("the BiH Agency") as an authority in the area of pharmaceuticals and medical devices used in medical practices in Bosnia and Herzegovina ("BiH").

Article 6

(Objectives)

The BiH Agency is established for the purpose of

a) Protecting and promoting public health care by ensuring a supply of quality, safe and efficient pharmaceuticals and medical devices for use in human medicine, and for the purpose of establishing a functional, coordinate and uniform system or regulation of pharmaceuticals and medical devices;

b) Establishing and supervising a unified market for pharmaceuticals and medical devices and ensuring their availability throughout the territory of BiH;

c) Implementing cooperation and providing professional assistance to the relevant State and Entities Ministerial Authorities responsible for public health care through outlining policies, preparing proposals and implementing national policies for use of pharmaceuticals and material devices in human medicine;

d) Making proposals and amendments to legislation in the area of pharmaceuticals and material devices, and harmonizing the regulations with the international standards;

e) Executing any other activities stipulated by this Law and regulations derived therefrom.

Article 7

(Role of the BiH Agency in the area of pharmaceuticals)

The role of the BiH Agency in the area of pharmaceuticals includes:

a) Issuing, renewing or cancelling and amending of marketing authorisation of pharmaceuticals;

b) Activities regarding laboratory testing of pharmaceuticals and providing professional expert evaluation of the quality of pharmaceuticals;

c) Issuing of good practice certificates (manufacturer, wholesale pharmacies, clinical, laboratory, transportation, etc.);

d) Registering or approving of clinical trials of pharmaceuticals and monitoring of adverse effects occurring during clinical trials;

e) Issuing of manufacturer of pharmaceuticals authorisation based on a certificate on complying with good manufacturer practice;

f) Issuing of wholesale marketing authorisation of pharmaceuticals based on a certificate on complying with good distribution practice (good wholesale pharmacies practice);

g) Establishing and maintaining an updated record of imported pharmaceuticals for which a marketing authorisation has not been issued in BiH;

h) Publishing an annual Register of pharmaceuticals containing the list of pharmaceuticals permitted for marketing in BiH;

i) Making recommendations for an essential pharmaceuticals list in Bosnia and Herzegovina necessary for protecting public health safety ("the list of essential pharmaceuticals in BiH);

j) Collecting information, analysing and responding to adverse effects of pharmaceuticals, or performing pharmacovigilance Activities;

k) Carrying out the assurance control of pharmaceuticals Activities;

l) Carrying out pharmaceutical inspection of pharmaceuticals of legal entities engaged in manufacturing and wholesale marketing of pharmaceuticals, in view of the issued authorities;

m) Organising information systems of pharmaceuticals, including establishing a database covering pharmaceuticals authorised for marketing in BiH, collecting data about sales and usage of pharmaceuticals and establishing a cooperation with international informational pharmaceuticals networks, as well as informing professionals and general public in the country about the pharmaceuticals in view of the current legislation, and participating in the international exchange of information regarding adverse effects of pharmaceuticals;

n) Compliance with European pharmacopoeia and monitoring development of pharmacopoeia in BiH;

o) With the approval of relevant authorities from the state or entities, assisting in the international exchange of information and keeping records of marketing of narcotic drugs and psychotropic substances;

p) Making recommendations for harmonising the legislation in the area of pharmaceuticals with legislation of the European Union and with the guidelines provided by international institutions;

r) Performing any other Activities in the area of pharmaceuticals in accordance with this Law and regulations derived therefrom.

Article 8

(Role of the BiH Agency in the area of medical devices)

The role of the BiH Agency in the area of medical devices:

a) Keeping a register of medical devices for the territory of BiH;

b) Keeping a register of manufacturers of medical devices for the territory of BiH;

c) Keeping a register of legal entities engaged in wholesale of medical devices for the territory of BiH;

d) Issuing of certificates of registering manufacturers of medical devices;

e) Issuing of certificates of registering legal entities engaged in wholesale of medical devices;

f) Issuing of certificates of registering medical devices in the Registry of medical devices;

g) Collecting information, analysing and responding to undesirable occurrences in application of medical devices, or materiovigilance of medical devices;

h) Assessing conformity and labelling of medical devices in BiH with harmonised European standards and technical regulations in accordance with the Technical Requirements and Conformity Assessment of Products Laws;

i) Carrying out professional inspection and supervision of manufacturing and wholesale marketing of medical devices, as well as of legal entities engaged in manufacturing or importing and wholesale marketing of medical devices in view of issued authorisations;

j) Organising an information system of medical devices, including establishing a database covering medical devices registered in the Registry of medical devices, collecting data about legal entities engaged in manufacturing or importing and wholesale marketing of medical devices, collecting data about sales and usage of medical devices, as well as data to enable rational usage of medical devices, and establishing a cooperation with international informational medical devices networks;

k) Performing any other Activities in the area of medical devices in accordance with this Law and regulations derived therefrom.

Article 9

(Control Laboratory of the BiH Agency)

(1) The control Laboratory of the BiH Agency shall carry out Activities regarding pharmaceuticals testing and quality assurance of pharmaceuticals and substances.

(2) The BiH Agency is entitled to engage other authorised laboratories to perform specific analysis that cannot be carried out within the BiH Agency for Pharmaceuticals and Medical Devices.

(3) The authorised laboratories referred to in paragraph (2) of this Article must be within OMCL network (Official Medicine Control Laboratories).

Article 20, paragraph (1)

(Committees of the BiH Agency)

(1) Committees of the BiH Agency are as follows:

a) Committee for pharmaceuticals,

b) Committee for medical devices,

c) Committee for clinical trials,

d) Committee for pharmacopoeia,

e) Other committees for dealing with particular issues.

Article 23

(Committee for pharmaceuticals)

(1) Committee for pharmaceuticals shall assess documentation regarding quality, safety and efficacy of each pharmaceutical enclosed to the application for obtaining a marketing authorisation, or for its renewal or amendment.

(2) Committee for pharmaceuticals shall recommend to the Professional Board a list of essential pharmaceuticals in BiH.

(3) Committee for pharmaceuticals shall consist of 15 members. Departments of Health from each Entity shall recommend seven members, and the Department of Health of Brčko District shall recommend one member.

Article 24

(Committee for clinical trials)

(1) Committee for clinical trials shall assess documentation enclosed to the application for obtaining permission for clinical trials of pharmaceuticals and to the application for registering the clinical trial, or an amendment or annex to an already registered and approved protocol of the clinical trial.

(2) Committee for clinical trials shall consist of seven members. Departments of Health from each Entity shall recommend three members, and the Department of Health of Brčko District shall recommend one member.

Article 25

(Committee for medical devices)

(1) Committee for medical devices shall assess documentation enclosed to the application for registering medical devices without a required CE mark in accordance with the Technical Requirements and Conformity Assessment of Products Laws, unless an authority ascertained by the Technical Requirements and Conformity Assessment of Products Laws has already done the assessment.

(2) Committee for medical devices shall assess documentation enclosed to application for obtaining permission to perform clinical trials of the medical device, or the application for amendment or annex to an already registered and approved protocol of the clinical trial.

(3) Committee for medical devices shall consist of nine members. Departments of Health from each Entity shall recommend four members, and the Department of Health of Brčko District shall recommend one member.

Article 26

(Committee for pharmacopoeia)

(1) Committee for pharmacopoeia shall follow development of the European pharmacopoeia, provide recommendations for a national contribution to the European pharmacopoeia and shall provide recommendations for pharmacopoeia of BiH.

(2) Committee for pharmacopoeia shall consist of seven members. Departments of Health from each Entity shall recommend one member, and the Department of Health of Brčko District shall recommend one member, Faculty of Pharmacy from each Entity shall recommend one member, and the Control Laboratory of the BiH Agency shall recommend two members.

Article 27

(Other permanent and temporary committees)

For the purpose of dealing with particular issues regarding pharmaceuticals and medical devices, the Agency Director may establish permanent or occasional committees with representatives from the Federation of Bosnia and Herzegovina

("the Federation of BiH"), the Republika Srpska ("the RS") and the Brčko District of Bosnia and Herzegovina.

CHAPTER V. PHARMACEUTICAL-INSPECTORIAL SUPERVISION

Article 124

(Pharmaceutical-inspectorial supervision)

(1) Pharmaceutical-inspectorial supervision over the implementation of this Law and legislation derived therefrom shall be performed by the pharmaceutical inspection, or the inspection formed within the BiH Agency.

(2) Duties of the pharmaceutical inspection, or inspection referred to in paragraph 1 of this Article shall be performed by pharmaceutical inspectors or the BiH Agency inspectors ("the pharmaceutical inspector/inspector).

(3) Methods of supervision referred to in paragraph 1 of this Article shall be prescribed by the Minister of Civil Affairs upon the recommendation by the Agency Director.

(4) Pharmaceutical-inspectorial supervision of pharmaceuticals and medical devices shall be determined by legislation in Entities or Brčko District.

Article 141

(Harmonization of entity regulations)

(1) Both Entities and Brčko District shall be required to harmonise legislation regarding pharmaceuticals and medical devices, in accordance with this Law, within 90 days from the date of entry into force of this Law.

(2) Until relevant by-laws have been adopted as stipulated by this Law, by-laws of each Entity and of Brčko District shall remain in force, unless they are contrary to the provisions of this Law.

19. The **Law on Ministries and Other Bodies of Administration of Bosnia and Herzegovina** (*Official Gazette of BiH*, 5/03, 42/03, 26/04, 42/04, 45/06, 88/07, 35/09, 59/09, 103/09, 87/12, 6/13, 19/16, 83/17).

For the purposes of this decision, the unofficial revised text prepared in the Constitutional Court is used. The relevant provisions of the mentioned Law read:

Article 1

This law shall establish the Ministries and shall identify administrative organisations and other institutions of Bosnia and Herzegovina (hereinafter: BiH) carrying out tasks and duties of administration within the competence of BiH, specify their scope of work, the manner of their management, as well as other issues concerning their functioning.

III - INDEPENDENT ADMINISTRATIVE ORGANISATIONS

Article 17(1) subparagraph 16

Independent administrative organisations shall be as follows:

16. Agency for Pharmaceuticals and Medical Devices of Bosnia and Herzegovina,

20. The **Constitution of Republika Srpska** (*Official Gazette of the RS*, 21/92, 28/94, 8/96, 13/96, 15/96, 16/96, 21/96, 21/02, 26/02 - correction, 30/02 - correction, 31/02, 69/02, 31/03, 98/03, 115/05, 117/05, 48/11 and 91/19 - Decision of the CC BiH). For the purposes of the present decision, the unofficial revised text of the regulations prepared in the Constitutional Court of BiH, as published in the official gazettes, for it was not published in all official languages and scripts, is used. The Constitution of Republika Srpska, as relevant, reads:

Article 37(1) and (2)

Everyone shall be entitled to health care.

The right to health care shall be guaranteed in conformity with law.

1. National Assembly

Article 68 subparagraph 12

The Republika Srpska shall regulate and ensure:

12) work relations, safety at work, employment, social insurance and other forms of social care, health care, soldiers and invalid protection, child and youth care, education, culture and cultural resources protection, physical culture;

Article 70(1) subparagraph 2

The National Assembly shall:

2. Enact laws, other regulations and general enactments.

Article 78

The National Assembly shall regulate its work and organisation and the manner of exercising the rights and duties of deputies.

21. The **Law on Pharmaceuticals and Medical Devices of Republika Srpska (***Official Gazette of the RS*, 118/21), as relevant, reads:

Subject of the Law

Article 1

This Law shall regulate the definitions of pharmaceuticals and medical devices for use in human medicine, production, testing and marketing of pharmaceuticals and medical devices, conditions and measures for ensuring the quality, safety and efficiency of pharmaceuticals and medical devices, establishment, scope and method of operation, competence of the Agency for pharmaceuticals and medical devices of Republika Srpska, supervision of pharmaceuticals, medical devices and legal entities engaged in production, testing or wholesale marketing of pharmaceuticals and medical devices, as well as other issues of importance in the area of pharmaceuticals and medical devices.

Application of the Law

Article 2(1) and (3)

(1) Healthcare is an activity of general interest for the Republika Srpska.

(3) This Law shall apply also to pharmaceuticals containing narcotic drugs and psychotropic substances as well as raw materials used for their production, unless regulated by a separate Law in compliance with international conventions regulating this type of pharmaceuticals.

AGENCY FOR PHARMACEUTICALS AND MEDICAL DEVICES

Institutional structure

Article 4

(1) This Law shall establish an Agency for Pharmaceuticals and Medical Devices of Republika Srpska ("the Agency") as an authority in the area of pharmaceuticals and medical devices used in medical practices in the Republic.

(2) The Agency is an independent administrative organization and shall have the status of a legal entity.

(3) The organization and work of the Agency shall be subject to the provisions of regulations governing the area of republican administration, unless otherwise regulated by this law.

Role of the Agency in the area of pharmaceuticals

Article 8

The role of the Agency in the area of pharmaceuticals shall include:

1) Issuing, renewing or cancelling and amending of marketing authorisation of pharmaceuticals,

2) Activities regarding laboratory testing of pharmaceuticals and providing professional expert evaluation of the quality of pharmaceuticals,

3) Issuing of good practice certificates (manufacturer, wholesale pharmacies, clinical, laboratory, transportation, etc.),

4) Registering or approving of clinical trials of pharmaceuticals and monitoring of adverse effects occurring during clinical trials,

5) Issuing of manufacturer of pharmaceuticals authorisation based on a certificate on complying with good manufacturer practice,

6) Issuing of wholesale marketing authorisation of pharmaceuticals based on a certificate on complying with good distribution practice (good wholesale pharmacies practice),

7) Establishing and maintaining an updated record of imported pharmaceuticals for which a marketing authorisation has not been issued in the Republic,

8) Publishing an annual Register of pharmaceuticals containing the list of pharmaceuticals permitted for marketing in the Republic,

9) Collecting information, analysing and responding to adverse effects of pharmaceuticals, or performing pharmacovigilance Activities,

10) Carrying out the assurance control of pharmaceuticals Activities,

11) Organising information systems of pharmaceuticals, including establishing a database covering pharmaceuticals authorised for marketing in the Republic, collecting data about sales and usage of pharmaceuticals and establishing a cooperation with international informational pharmaceuticals networks, as well

as informing professionals and general public about the pharmaceuticals in view of the current legislation, and participating in the international exchange of information regarding adverse effects of pharmaceuticals,

12) Compliance with European pharmacopoeia,

13) Assisting in the international exchange of information and keeping records of marketing of narcotic drugs and psychotropic substances, with the consent of the competent republican bodies,

14) Making recommendations for harmonising the legislation in the area of pharmaceuticals with legislation of the European Union and with the guidelines provided by international institutions,

15) Performing any other Activities in the area of pharmaceuticals in accordance with this Law and regulations derived therefrom.

Role of the Agency in the area of medical devices

Article 9

The role of the Agency in the area of medical devices shall include:

1) Keeping a register of medical devices for the territory of Republic,

2) Keeping a register of manufacturers of medical devices for the territory of Republic,

3) Keeping a register of legal entities engaged in wholesale of medical devices for the territory of Republic,

4) Issuing of certificates of registering manufacturers of medical devices for the territory of Republic,

5) Issuing of certificates of registering legal entities engaged in wholesale of medical devices for the territory of Republic,

6) Collecting information, analysing and responding to undesirable occurrences in application of medical devices, or materiovigilance of medical devices,

7) Assessing conformity and labelling of medical devices in the Republic with harmonised European standards and technical regulations adopted based on regulations governing the area of technical requirements for products and assessment of compliance,

8) Carrying out professional inspection and supervision of manufacturing and wholesale marketing of medical devices, as well as of legal entities engaged in manufacturing or importing and wholesale marketing of medical devices in view of issued authorisations,

9) Organising an information system of medical devices, including establishing a database covering medical devices registered in the Registry of medical devices for the territory of Republic, collecting data about legal entities engaged in manufacturing or importing and wholesale marketing of medical devices, collecting data about sales and usage of medical devices, as well as data to enable rational usage of medical devices, and establishing a cooperation with international informational medical devices networks,

10) Performing any other Activities in the area of medical devices in accordance with this Law and regulations derived therefrom.

Control Laboratory of the Agency

Article 10

(1) The Control Laboratory within the Agency and other laboratories authorized by the Minister shall carry out Activities regarding pharmaceuticals testing and quality assurance of pharmaceuticals and substances.

(2) The Agency is entitled to engage other authorised laboratories to perform specific analysis that cannot be carried out within the Agency.

(3) The authorised laboratories referred to in paragraph (2) of this Article must be within OMCL network (Official Medicine Control Laboratories).

Committee for pharmaceuticals

Article 23

(1) Committee for pharmaceuticals shall assess documentation regarding quality, safety and efficacy of each pharmaceutical enclosed to the application for obtaining a marketing authorisation, or for its renewal or amendment.

(2) Committee for pharmaceuticals shall recommend to the Professional Board of the Agency a list of essential pharmaceuticals in the Republika Srpska.

(3) Committee for pharmaceuticals shall consist of 15 members.

Committee for clinical trials

Article 24

(1) Committee for clinical trials shall assess documentation enclosed to the application for obtaining permission for clinical trials of pharmaceuticals and to the application for registering the clinical trial, or an amendment or annex to an already registered and approved protocol of the clinical trial.

(2) Committee for clinical trials shall consist of seven members.

Committee for medical devices

Article 25

(1) Committee for medical devices shall assess documentation enclosed to the application for registering medical devices without a required CE mark in accordance with the regulation governing the area of technical requirements for products and assessment of compliance in accordance with this Law.

(2) Committee for medical devices shall assess documentation enclosed to application for obtaining permission to perform clinical trials of the medical device, or the application for amendment or annex to an already registered and approved protocol of the clinical trial.

(3) Committee for medical devices shall consist of nine members.

Committee for pharmacopoeia

Article 26

(1) Committee for pharmacopoeia shall follow development of the European pharmacopoeia.

(2) Committee for pharmacopoeia shall consist of seven members.

SUPERVISION

Supervision over the implementation and enforcement of laws

Article 124

(1) The Ministry shall carry out administrative supervision over the implementation of this Law.

(2) The inspection supervision over the implementation of this Law and the regulations derived therefrom shall be carried out by the pharmaceutical inspector, in accordance with the provisions of the law regulating inspection supervision.

Timeframe for harmonisation

Article 135

(1) Legal entities, authorisation holders for the manufacture and wholesale marketing of pharmaceuticals, as well as the manufacture and wholesale marketing of medical devices, shall be required to harmonise their operations with the provisions of this Law within six months from the date of entry into force of this Law.

(2) Legal entities referred to in paragraph 1 of this Article shall be required to harmonise their operations with good practices within one year from the date of entry into force of this Law.

(3) Valid authorisations for marketing, manufacture and wholesale, i.e. import, issued by the competent authorities, shall remain in force until the date on which they have expired.

Cessation of the Previous Law

Article 136

The Law on Pharmaceuticals ("Official Gazette of the Republika Srpska", 19/01, 113/05 and 34/08) shall cease to have effect on the day this Law comes into force.

22. The **Law Amending the Law on Republic Administration (***Official Gazette of the Republika Srpska, 15/22*), as relevant, reads:

Article 1

In the Law on Republic Administration ("Official Gazette of Republika Srpska", 115/18 and 111/21) in Article 39, paragraph 20, after the word: "investments" comma and new paragraph 21 shall be added to read:

"21) Agency for pharmaceuticals and medical devices of the Republika Srpska".

Article 2

After Article 58a, new Article 58b shall be added to read:

“Article 58b

(1) The Agency for pharmaceuticals and medical devices of the Republika Srpska shall carry out Activities of issuing renewing or cancelling and amending of marketing authorisation of pharmaceuticals, Activities regarding laboratory testing of pharmaceuticals and providing professional expert evaluation of the quality of pharmaceuticals, issuing of good practice certificates (manufacturer, wholesale pharmacies, clinical, laboratory, transportation, etc.), registering or approving of clinical trials of pharmaceuticals and monitoring of adverse effects occurring during clinical trials, issuing of manufacturer of pharmaceuticals authorisation based on a certificate on complying with good manufacturer practice, issuing of wholesale marketing authorisation of pharmaceuticals based on a certificate on complying with good distribution practice (good wholesale pharmacies practice), establishing and maintaining an updated record of imported pharmaceuticals for which a marketing authorisation has not been issued in the Republic, publishing an annual Register of pharmaceuticals containing the list of pharmaceuticals permitted for marketing in the Republic, collecting information, analysing and responding to adverse effects of pharmaceuticals, or performing pharmacovigilance Activities, carrying out the assurance control of pharmaceuticals Activities, organising information systems of pharmaceuticals, including establishing a database covering pharmaceuticals authorised for marketing in the Republic, collecting data about sales and usage of pharmaceuticals and establishing a cooperation with international informational pharmaceuticals networks, as well as informing professionals and general public about the pharmaceuticals in view of the current legislation, and participating in the international exchange of information regarding adverse effects of pharmaceuticals, compliance with European pharmacopoeia, assisting in the international exchange of information and keeping records of marketing of narcotic drugs and psychotropic substances, with the consent of the competent republican bodies, making recommendations for harmonising the legislation in the area of pharmaceuticals with legislation of the European Union and with the guidelines provided by international institutions, keeping a register of medical devices for the territory of Republic, keeping a register of manufacturers of medical devices for the territory of Republic, keeping a register of legal entities

engaged in wholesale of medical devices for the territory of Republic, issuing of certificates of registering manufacturers of medical devices for the territory of Republic, issuing of certificates of registering legal entities engaged in wholesale of medical devices for the territory of Republic, collecting information, analysing and responding to undesirable occurrences in application of medical devices, or materiovigilance of medical devices, assessing conformity and labelling of medical devices in the Republic with harmonised European standards and technical regulations adopted on the basis of regulations governing the area of technical requirements for products and assessment of compliance, carrying out professional inspection and supervision of manufacturing and wholesale marketing of medical devices, as well as of legal entities engaged in manufacturing or importing and wholesale marketing of medical devices in view of issued authorisations, organising an information system of medical devices, including establishing a database covering medical devices registered in the Registry of medical devices for the territory of Republic, collecting data about legal entities engaged in manufacturing or importing and wholesale marketing of medical devices, collecting data about sales and usage of medical devices, as well as data to enable rational usage of medical devices, and establishing a cooperation with international informational medical devices networks, and performing any other Activities in the area of medical devices in accordance with the law.

(2) The Agency for pharmaceuticals and medical devices of the Republika Srpska shall be an independent administrative organization with the status of a legal entity".

V. Admissibility

23. In examining the admissibility of the request, the Constitutional Court invoked the provision of Article VI (3) (a) of the Constitution of Bosnia and Herzegovina, which reads:

a) The Constitutional Court shall have exclusive jurisdiction to decide any dispute that arises under this Constitution between the Entities or between Bosnia and Herzegovina and an Entity or Entities, or between institutions of Bosnia and Herzegovina, including but not limited to:

- Whether an Entity's decision to establish a special parallel relationship with a neighbouring state is consistent with this Constitution, including provisions concerning the sovereignty and territorial integrity of Bosnia and Herzegovina.

- Whether any provision of an Entity's constitution or law is consistent with this Constitution.

Disputes may be referred only by a member of the Presidency, by the Chair of the Council of Ministers, by the Chair or a Deputy Chair of either chamber of the Parliamentary Assembly, by one-fourth of the members of either chamber of the Parliamentary Assembly, or by one-fourth of either chamber of a legislature of an Entity.

24. The request for review of constitutionality was filed by the Chairman of the Presidency of Bosnia and Herzegovina, at the time of filing the request, which means that the request was submitted by an authorised person within the meaning of Article VI (3) (a) of the Constitution of Bosnia and Herzegovina. In addition, the Constitutional Court observes that the applicant requested the review of constitutionality of the RS Law on Pharmaceuticals, wherefrom it follows that it undisputed that the Constitutional Court has competence to decide.

25. Therefore, having regard to the provisions of Article VI (3) (a) of the Constitution of Bosnia and Herzegovina and Article 19 paragraph (1) of the Rules of the Constitutional Court, the Constitutional Court established that this request is admissible as it was submitted by an authorised person. In addition, there is not a single formal reason referred to in Article 19, paragraph (1) of the Rules of the Constitutional Court, which would render the request inadmissible.

VI. Merits

26. The applicant states that the challenged laws are not in conformity with the provisions of Article I (2), Article I (4), Article II (4), Article III (3) (b) and Article III (5) (a) of the Constitution of Bosnia and Herzegovina. Namely, the applicant claims that the National Assembly passed the challenged laws without a valid constitutional ground and contrary to the provisions of the Constitution of BiH and the laws of Bosnia and Herzegovina, as “the decisions of the institutions of Bosnia and Herzegovina”. The applicant claims the laws are contrary to the principle of the rule of law under Article I (2) of the Constitution of BiH. In addition, the applicant alleges that the challenged laws are contrary to the provision of Article III (3) (b) of the Constitution of BiH, which prescribes that the Entities and any subdivisions thereof shall comply fully with this Constitution and with the decisions of the institutions of Bosnia and Herzegovina.

27. On the other hand, the National Assembly contested the allegations made in the request by indicating that the Parliamentary Assembly did not have the responsibility to pass the Law on Pharmaceuticals of BiH. In addition, the National Assembly stated that it, in passing the challenged laws, acted in accordance with the provisions of the RS Constitution and the responsibilities of the Republika Srpska.

28. In view of the aforementioned, the Constitutional Court deems that the present case primarily raises the issue of conformity of the challenged laws with the provisions of Article I (2) and Article III (3) (b) of the Constitution of Bosnia and Herzegovina, which read as follows:

Article I (2)

2. Democratic Principles

Bosnia and Herzegovina shall be a democratic state, which shall operate under the rule of law and with free and democratic elections.

Article III (3) (b)

b) The Entities and any subdivisions thereof shall comply fully with this Constitution, which supersedes inconsistent provisions of the law of Bosnia and Herzegovina and of the constitutions and law of the Entities, and with the decisions of the institutions of Bosnia and Herzegovina. The general principles of international law shall be an integral part of the law of Bosnia and Herzegovina and the Entities.

29. The Constitutional Court recalls that it has already taken a clear position in its case law about the constitutional obligation to uphold state laws. Similarly, in Decision no. *U-14/04,* the Constitutional Court indicated that "the passing of Entities' laws contrary to the procedure prescribed under the State laws raises the issue of constitutionality of such laws within the meaning of the provisions of Article III (3) (b) of the Constitution of Bosnia and Herzegovina, and that the obligations imposed under the State laws have to be complied with" (see, the Constitutional Court, Decision on Admissibility and Merits no. *U-14/04* of 29 October 2010, published in the *Official Gazette of BiH*, 23/05). The Constitutional Court reaffirmed this position also in Decision no. *U-2/11* (see, the Constitutional Court, Decision on Admissibility and Merits no. *U-2/11* of 27 May 2011, paragraph 52, published in the *Official Gazette of BiH*, 99/11). In that decision, the Constitutional Court indicated again the following:

"[…] the laws of Bosnia and Herzegovina passed by the Parliamentary Assembly of Bosnia and Herzegovina are being considered "decisions of the institutions of Bosnia and Herzegovina" under Article III (3) (b) of the Constitution of Bosnia and Herzegovina, and the adoption of the laws by the Entities or any subdivisions thereof in Bosnia and Herzegovina contrary to the procedure prescribed by the State laws might challenge the issue of compliance with Article III (3) (b) of the Constitution of Bosnia and Herzegovina, pursuant to which the Entities and any subdivisions thereof are obliged to comply, *inter alia*, (and) with the decisions of the institutions of Bosnia and Herzegovina. If held otherwise, besides completely bringing into question the authority of the institutions of Bosnia and Herzegovina, it would also challenge the principle referred to in Article I (2) of the Constitution of Bosnia and Herzegovina under which: "Bosnia and Herzegovina shall be a democratic state, which shall operate under the rule of law". In that case a question might rightly be posed regarding the purpose of the State laws (e.g. the laws in the field of privatisation, operations of the insurance companies, indirect taxation, etc.) if the entities or any subdivisions thereof in Bosnia and Herzegovina could pass laws violating or evading obligations imposed on the entities or any subdivisions thereof in Bosnia and Herzegovina by the provisions of the State legislation, i.e. laws adopted at the level of the institutions of Bosnia and Herzegovina. Therefore, the Entities (and any subdivisions thereof in Bosnia and Herzegovina) must comply with the obligations imposed on them through the laws passed by the institutions of Bosnia and Herzegovina. The fact that such obligations have not been complied with might result in the breach of the provisions of the Constitution of Bosnia and Herzegovina."

30. The Constitutional Court points out that the National Assembly in its reply to the request argues that the areas of medicines and medical devices are not within the responsibility of the institutions of Bosnia and Herzegovina (paragraph 16). The Court further notes that the subject matter of the applicant's request is limited to the question of the constitutionality of the RS Law on Pharmaceuticals and the Law on Amendments to the Law on RA. Since the Court's scope of examination is limited to the applicant's request, the Court will consider the respondent's allegations only if those are directly connected with the request and do not go beyond its subject matter. In this view, the Court concludes that in the present case it was not called upon to decide on the question of constitutionality of the Law on Pharmaceuticals of BiH. Therefore, the Court will

not delve into the issue of the constitutional basis for the BiH Law on Pharmaceuticals. The Court will examine whether the RS, by adopting the impugned laws, complied with the decisions of the Institutions of Bosnia and Herzegovina, as required by Article III (3) (b) and Article I (2) of the Constitution of Bosnia and Herzegovina.

31. The Constitutional Court observes that, first, it is necessary to consider whether the challenged RS Law on Pharmaceuticals regulates the same subject matter as the BiH Law on Pharmaceuticals. In that respect, the Constitutional Court observes that, based on the contents of the provisions of Articles 1, 2, 4, 8-10, 23-26 and 124 of the RS Law on Pharmaceuticals, it follows that those provisions pertain to the same issues referred to in the area of pharmaceuticals and medical devices, which was already regulated by the provisions of Articles 1, 6-9, 20, 23-27 and 124 of the BiH Law on Pharmaceuticals. In addition, the RS Law on Pharmaceuticals and the Law on Amendments to the Law on RA provide the establishment of the responsibility of the Agency and other Entity's authorities for the implementation of the aforementioned provisions of law, in respect of which the responsibility of BiH Agency and other state authorities already exists. Furthermore, the Agency has equal responsibilities and powers as the BiH Agency. Having in mind such a state of affairs, the Constitutional Court finds it apparent that the challenged laws pertain to the same matter as that prescribed under the BiH Law on Pharmaceuticals.

32. The Constitutional Court recalls that the provision of Article 141, paragraph 1 of the BiH Law on Pharmaceuticals prescribes that the Entities, and the Brčko District, "shall be obliged to harmonise, within 90 days from the day of entry into force of this Law, the regulations in the area of pharmaceuticals and medical devices with this Law". Seen in light of the jurisprudence recalled in paragraph 29 above, non-compliance by the legislature of the RS with this duty to harmonise the regulations in the area of pharmaceuticals and medical devices with the BiH Law on Pharmaceuticals can raise questions of constitutionality. The impugned legislation enacted by the RS National Assembly essentially restates the wordings of the BiH Law on Pharmaceuticals and creates an institution akin to the authority created under the BiH Law on Pharmaceuticals that is vested with the powers to execute the law. A reasonable interpretation of 'harmonisation' in the mentioned Article of the BiH Law on Pharmaceuticals cannot be held to accommodate within its scope, the creation of a separate legislative framework in the area of pharmaceuticals and medical devices, and an executive authority for the implementation of such framework. This finding is buttressed by a consideration of one of the purposes of creating the Agency for Pharmaceuticals and Medical Devices of Bosnia and Herzegovina under the BIH Law on Pharmaceuticals, viz. the "[e]stablishing and supervising a unified market for pharmaceuticals and medical devices and

ensuring their availability throughout the territory of BiH" (Article 6 (b), BIH Law on Pharmaceuticals).

33. Furthermore, the Constitutional Court notes that the allegations made in the reply to the request, which referred to the Law on Pharmaceuticals of the Federation of BiH, namely that "the applicant did not challenge the constitutionality of that Law", are irrelevant. The applicant's decision to challenge or not to challenge a law before the Constitutional Court is immaterial to both the request and the arguments forwarded by the National Assembly.

34. Furthermore, the Constitutional Court observes that, in the reply to the request, the National Assembly also pointed to "the importance and the interest that the area of pharmaceuticals and medical devices has for the citizens of the Republika Srpska", and that it is one of the reasons why the challenged laws were passed. In that respect, the Constitutional Court indicates that the general aim of the single policy for pharmaceuticals and medical devices in Bosnia and Herzegovina is to ensure the availability of quality, safe and effective medicines and medical devices to all the citizens and their usage throughout Bosnia and Herzegovina in a rational fashion. This aim is accomplished, among other things, through legislation and organisation (see, "Pharmaceuticals and Medical Devices Policy in Bosnia and Herzegovina", document of the BiH Council of Ministers dated 27 July 2010, published in the *Official Gazette of BiH*, 55/11; available here). Moreover, this document reads: "all participants in the healthcare system […] should work in partnership on promoting the objectives of the Pharmaceuticals and Medical Devices Policy", and "be engaged and fulfil their respective obligations", as well as "be responsible in the implementation of the Pharmaceuticals and Medical Devices Policy", of which the Agency for Pharmaceuticals of BiH is in charge. Thus, the Constitutional Court observes that the BiH Parliamentary Assembly, by adopting the BiH Law on Pharmaceuticals, kept in mind precisely the importance that the area of pharmaceuticals and medical devices has for all citizens of BiH, and not only for the Republika Srpska. This, certainly, as already suggested, does not bring into question the possibility for an Entity to regulate further this area, only in the part though where a certain issue has not already been regulated by the state law, or to prescribe which authority has been in charge of this area in the Entities. However, this can be done only in the part where the responsibility of the BiH Agency has not already been prescribed.

35. Therefore, the Constitutional Court holds that the Constitution of BiH contains no provision based on which it could be concluded that the challenged laws passed by the National Assembly are constitutional. According to the principle of the rule of law under Article I (2) of the Constitution of Bosnia and Herzegovina, the Entities shall comply with the laws at the level of Bosnia and

Herzegovina and, under Article III (3) (b) of the Constitution of Bosnia and Herzegovina, the Entities shall comply fully with the decisions of the institutions of Bosnia and Herzegovina.

36. In view of all the aforementioned, the Constitutional Court concludes that the National Assembly, in adopting the challenged laws, acted in contravention of Article I (2) and Article III (3) (b) of the Constitution of Bosnia and Herzegovina with regard to the RS Law on Pharmaceuticals and the Law on Amendments to the Law on RA. Therefore, the mentioned laws are contrary to Article I (2) and Article III (3) (b) of the Constitution of Bosnia and Herzegovina.

Other allegations

37. Finally, the Constitutional Court observes that the applicant also challenged the constitutionality of the challenged laws from the aspect of Articles I (4), II (4) and III (5) (a) of the Constitution of BiH. However, the Constitutional Court holds that, considering the already adopted conclusions, there is no need to examine separately the said allegations.

VII. Conclusion

38. The Constitutional Court concludes that the RS Law on Pharmaceuticals and the Law on Amendments to the Law on RA, which were passed by the National Assembly, are not in conformity with Article I (2) of the Constitution of Bosnia and Herzegovina and Article III (3) (b) of the Constitution of Bosnia and Herzegovina.

39. Pursuant to Article 64 (4) of the Rules of the Constitutional Court, the legal effect of the Decision on interim measure no. *U-17/22* of 6 July 2022 shall cease.

40. Pursuant to Article 59 (1) and (2) and Article 61 paragraphs (2) and (3) of the Rules of the Constitutional Court, the Constitutional Court decided as set out in the enacting clause of this decision.

41. Based on Article 43 (1) of the Rules of the Constitutional Court, Vice-President of the Constitutional Court Zlatko M. Knežević gave a statement of dissent.

42. Pursuant to Article VI (5) of the Constitution of Bosnia and Herzegovina, the decisions of the Constitutional Court shall be final and binding.

Valerija Galić
President
Constitutional Court of Bosnia and Herzegovina