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THE ECONOMIC, COMMERCIAL AND FINANCIAL AFFAIRS COMMITTEE

REPORT*
"Cooperation in the Field of the Pharmaceutical Industry in the BSEC Member States"

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I. INTRODUCTION

1. The right to physical and mental health is a fundamental human right. The Preamble of the World Health Organization (WHO) Constitution states that "the extension to all peoples of the benefits of medical, psychological and related knowledge is essential to the fullest attainment of health. Governments have a responsibility for the health of their peoples which can be fulfilled only by the provision of adequate health and social measures."

2. The pharmaceutical industry is part of the healthcare sector and is responsible for the discovery, development and manufacturing of medications and vaccines by public and private organizations. With its two large segments – (1) manufacturing and distribution and (2) research and development, the industry is one of the key players in the field of healthcare and contributes to the economic development of the countries.

3. The pharmaceutical industry today is one of the most innovative sectors of the economy in the world, with the important role in developing new and improved medicines and vaccines to prevent and treat diseases. Pharmaceutical manufacturers are involved in a meaningful and important mission to improve the healthcare conditions and quality of life of the population throughout the world.

4. The United Nation 2030 Agenda for Sustainable Development adopted in 2015, influenced and framed the work of all national and international entities and streamlined them towards the implementation of Sustainable Development Goals (SDGs). The comprehensive SDG 3 on ensuring healthy lives and promoting well-being for all, at all ages and its 13 targets concentrate on main health priorities. Target 3.8 of the Goal 3 focuses on achieving universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all. The target 3b focuses on promotion of the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries and their access to affordable essential medicines and vaccines.

5. During the unprecedented global health crisis of the COVID-19 pandemic, the world at large and the pharmaceutical industry in particular are facing the challenge of a rapid and significant reaction to save the lives of millions of people in the world. Despite the breakthrough of the pharmaceutical industry and its progress in improving healthcare, the sudden emergence of a global challenge showed the urgent necessity for readiness to respond through a speedy development of vital pharmaceutical products. The pandemic has demonstrated the immediate need to transform domestic health care and social security systems and ensure their effective involvement in international processes.

6. Taking into consideration the relevance of the topic and the importance of further strengthening the cooperation in the sphere of pharmaceutics in the BSEC Member States, the Fifty-Sixth meeting of the PABSEC Economic, Commercial, Technological and Environmental Affairs Committee, held on 17 March 2021, took the decision to discuss "Cooperation in the Field of the Pharmaceutical Industry in the BSEC Member States".

7. As ensuring healthy lives and the well-being of the peoples of the Black Sea region represents a major aim for the economic development of the BSEC Member States, the Parliamentary Assembly of the Black Sea Economic Cooperation has considered topics concerning the public health in the BSEC Region, in the course of its activities. Due to the vital importance of these topics, the Assembly prepared the Reports and Recommendations of all the three Committees,

calling for further economic cooperation and adequate measures and reforms, at the national level, along with the cooperation with international and regional specialized organizations.[1]

8. The present Report uses the information from the national delegations of the Republic of Azerbaijan, Republic of Bulgaria, the Hellenic Republic, the Republic of Moldova, Romania, the Russian Federation, the Republic of Serbia, the Republic of Turkey and Ukraine. It also uses the research material, the reports of relevant international organizations, as well as the relevant information from various Internet sources.

II. PHARMACEUTICAL INDUSTRY - MAIN TRENDS

9. The pharmaceutical industry is at the forefront of innovation of the economy and science as its activities are aimed at improving the quality of life of the population and their life expectancy. The progress made by the medical science during the last century contributes to the improvement of the healthcare. Today, the pharmaceutical sector comprises large pharmaceutical companies, a robust pharmaceurical market and strong research and development potential. Every year, medicines and vaccines prevent an increase in mortality. The pharmaceutical research and development based on innovative methods, play an important role in the development of medicines and vaccines for the prevention and treatment of diseases, as well as in improving the already existing medicines and therapies. Billion dollar investments and hours of hard work by scientists expand scientific horizons which helps enhance the healthcare globally and contribute to the sustainable growth of the well-being of peoples.

10. The global pharmaceutical market has experienced significant growth in recent years, with particularly intensive growth of modern biotechnology. The industry is one of the key players in public health and one of the most influential and profitable economic sectors. According to the estimates of the World Trade Organization (WTO), the trade in medical products was about 2 trillion USD and accounted for 5% of the total world trade and approximately 1.4% of the World GDP in 2019. Available data also show the immense growth of the sector in just two decades, as of end 2020 - the total global pharmaceutical market was estimated at about 1.27 trillion USD, while its value was 390 billion USD, in 2001.The most influential factors stimulating the growth of the global pharmaceutical market are the rise of the world's population, the growth of the senior population, the increase of global life expectancy, which rose from 66.8 years in 2000, to 73.3 years in 2019, the immense scientific progress, the technological advancements in manufacturing processes, the major investments in research and development, the increase of per capita healthcare expenditure, the growing intention of people to lead a healthy lifestyle, etc. In addition, the trends of telemedicine and e-health which have already started emerging before the pandemic, accelerated substantially through the pandemic and boosted the pharmaceutical industry.

11. It should be underlined that the pharmaceutical industry is a highly competitive one, with very high investments in the process of medicine development. According to the International

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[1] *The Assembly adopted the following Recommendations on the healthcare issues: Recommendation 44/2000 "Cooperation in the Field of Public Health among the BSEC Member-Countries", Recommendation 157/2017 "The Role of the Parliaments in Providing Sustainable Healthcare Systems in the BSEC Member States", Recommendation 176/2020 "The Role of Parliaments in Combating Pandemic - Economic Aspects", Recommendation 177/2020 "The Role of Parliaments in Combating Pandemic – Legal and Political Aspects" and Recommendation 178/2020 "The Role of Parliaments in Combating Pandemic - Social Aspects".*

Federation of Pharmaceutical Manufacturers and Associations (IFPMA), these expenditures were almost 150 billion USD in 2017. A more recent study in 2020, estimated that the median cost of getting a new drug into the market was 985 million USD, and the average cost was 1.3 billion USD. The IFPMA 2021 Report states that compared with other high-technology industries, the annual R&D expenditure by the biopharmaceutical industry is 7.3 times greater than that of the aerospace and defense industries, 6.5 times more than that of the chemical industry, and 1.5 times more than that of the software and computer services industry.

12. All the new medicines introduced into the market are the result of complex research and development processes. It takes 10 to 15 years to develop a new medicine or vaccine and it is estimated that only 1 - 2 of every 10000 substances manufactured in laboratories will successfully pass all the necessary stages of development. Before a newly invented medicine enters the market, it must go through several phases of clinical trials. The implementation of innovative projects is impossible without meeting a number of requirements, such as attracting high-class scientists, political and financial stability, the existence of adequate regulatory framework that protects and encourages innovation. Therefore, compared to other industries, the pharmaceutical industry accounted for the bulk of research and development investment, even during the economic and financial crisis.

13. According to leading experts from "Fortune Business Insight", the value of the global pharmaceutical industry was 1.12 trillion USD in 2020 and will reach 1.57 trillion USD by 2023. There is a positive trend in the average annual growth rate of 6%. At the same time, the employment of the population in the pharmaceutical industry amounted to 4.4 million people, which is 0.1% of the working population of the planet. As the overall annual prescription drug revenue and R&D expenditures show, these companies are able to collectively generate investment and turn new scientific innovations into validated treatments. In fact, the leading pharmaceutical companies like Roche, Novartis, Pfizer, etc. re-invest up to 20.8% of medication sales in the development of new pharmaceutical products.

14. Regulating pharmaceutical markets in an ever-changing environment is a complex matter that involves the dynamic relationship of various involved actors, from global and national regulators, pharmaceutical companies, health care institutions (private and state-owned), pharmaceutical associations, wholesalers, distributors, retailers, scientists, researchers, patients, civil society organizations, academia, etc. For the normal functioning of the health system, in addition to undisturbed medicines supply, it is necessary to systemically secure the functional and efficient connection of the three pillars on which the entire pharmaceutical market rests: producers, wholesalers and healthcare institutions.

15. While regulating pharmaceutical markets, the governments must find a delicate balance between industrial and health policies and reconcile sometimes conflicting interests. Public health is to be protected and improved by guaranteeing patient access to safe and effective medicines and by improving the quality of care. Governments have to stimulate the pharmaceutical industry, by supporting research and development, by a continuous employment in the pharmaceutical sector, etc. The role of the government is also to provide access to affordable medicines and to tackle potential medicine shortages. According to the WHO estimates, nearly 2 billion people have no access to basic medicines, and half of the world lacks access to essential health services. Pharmaceuticals consume a significant proportion of healthcare expenditure and account for 20% to 60% of health expenditures in low and middle-

income countries, compared with 18%, in the countries of the Organization for Economic Cooperation and Development (OECD).

16. The increasing globalization of trade and the merging of pharmaceutical companies are internationalizing the pharmaceutical production. Thus, the need arises for further global regulation of the sector. The WHO is the institution in the United Nations system in the field of global health governance that elaborates global norms and standards for countries worldwide in healthcare and sanitation spheres. The WHO has kept a list of essential medicines since 1977, which is updated every two years and functions as a guide for the procurement and supply of medicines. In addition, the Organization has introduced the Good Manufacturing Practices (GMP) that cover areas from development and production, to distribution, inspection and quality control of medicines. Maintaining high standards at all stages of the production process, stimulates innovation, renewal of production facilities and a high-quality personnel training. The GMP standards protect consumers by setting norms for high quality products and serve as a guarantee that the released products are safe and effective.

17. Common international standards in the global development of pharmaceuticals are of the utmost importance. Thus, the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) set forth global standardisation and harmonization guidelines. From the BSEC Member States, representatives of legislative and administrative authorities of the Republic of Armenia, the Republic of Azerbaijan, the Republic of Moldova, the Russian Federation and the Republic of Turkey participate in this structure as members and observers, while the EU member States participate collectively as the European Union. Also the role of the Pharmaceutical Inspection Cooperation Scheme (PIC/S) is to be considered, as a non-binding, informal cooperative arrangement between states' regulatory authorities in the field of GMP of medicinal products for human or veterinary use. The purpose of the structure is to harmonise the inspection procedure worldwide, by implementing the same standards, recommendations in the field of GMP, and provide inspectors' training and development. From the BSEC Member States, regulatory authorities from the Hellenic Republic, Romania, the Republic of Turkey and Ukraine participate in PIC/S**.**

18. The trend of spreading substandard or falsified medicines has increased due to globalized trade, use of information technologies and broad use of Internet medicine. This tendency presents a serious public health risk, as well as a violation of intellectual property and damage to a legitimate economy and to the environment. According to the joint OECD and the European Union Intellectual Property Office Study (2019), the value of global trade in counterfeit pharmaceuticals reached 4.4 billion USD in 2016, which represents 0.84% of the total world-wide imports in pharmaceutical products.

19. The COVID-19 pandemic became the largest health shock for the whole world. The pandemic had a negative impact on the pharmaceutical industry and became a catalyst for the existing problems in the field of health services, shortage of medicines, healthcare equipment, staff, diagnostics and distribution and transport services. The pandemic has wreaked havoc on enterprises and supply chains due to exceptional security and isolation measures. Differences and inequalities among and within countries in healthcare and pharmaceuticals became aggravated. On the other hand, due to the coronavirus pandemic, many new drugs have appeared on the market, that helped in the fight against the consequences of the COVID-19. Thus, trends in the global pharmaceutical market in the context of the pandemic, readjusted modern pharmaceutical industry, by initiating new medicines to respond quickly to today's challenges,

at the highest possible level. After the shock of the pandemic and its first wave, the pharmaceutical market began to gradually stabilize. Pharmaceutical manufacturers have shifted research and development priorities. The COVID-19 pandemic has demonstrated the need of innovative approaches to vaccine development. In order to develop new therapeutic solutions - vaccines and medicines against COVID-19, many processes have been accelerated and now proceed in a fundamentally different way. Adequate pandemic preparedness and response ensures safety and health of people. The development of coronavirus vaccines in a record time, through innovative approaches and accelerated, parallel testing processes, has resulted in an effective crisis management and the reduction of number of deaths.

20. Another aspect to be taken into consideration, is the implication of presence of pharmaceuticals in the environment. It is to be closely monitored since pharmaceuticals in the environment are expected to rise with an increase in pharmaceutical consumption, which could have significant implications for the structure and functioning of ecosystems. In line with Sustainable Development Goal 12, to "ensure sustainable consumption and production patterns", it is important that the states introduce rational models of consumption and production of pharmaceuticals to minimize the negative impact on the environment. The maximum efficiency of the manufactured products and services throughout the life cycle must be ensured, without compromising the needs of the future generations.

III. PHARMACEUTICAL INDUSTRY- REGIONAL FRAMEWORK

a) The BSEC Framework

21. Strengthening cooperation in the sphere of health care and pharmaceutics has been one of the priority tasks for the Organization of the Black Sea Economic Cooperation (BSEC). The public health and pharmaceuticals areas of cooperation have, so far, been discussed in three Meetings of the Ministers in charge of Healthcare of the BSEC Member States, namely: in Athens, in 2014, Chisinau in 2015 and in Moscow in 2016. The Ministers in charge of Healthcare and Pharmaceutics of the BSEC Member States in the Declaration on Cooperation in the Sphere of Quality, Effectiveness and Safety Assurance of Medicines, adopted in Moscow in 2016, put a special emphasis on the importance of quality, effectiveness and safety assurance of medicines that are in circulation in the territories of the BSEC Member States, as well as to the substandard, falsified and counterfeit medicines that are perceived as serious threats to public health.

22. In the strategic document "The BSEC Economic Agenda - Towards an Enhanced BSEC Partnership" adopted in 2012, the Goal 7 is dedicated to healthcare and pharmaceutics. The main activities of the BSEC Member States in the field of healthcare and pharmaceutics are conducted by the respective Working Group (WG) formed in 1996, with representatives from all Member States. Its main tasks are to contribute to intensified collaboration in this field, through strengthening the cooperation in public health and pharmaceutics, preventing the spread of infectious diseases, exchanging experiences of the health system to achieve standards of health and well-being, sanitary protection, etc., in the BSEC Member States and BSEC Region.

23. Currently, the BSEC WG on Healthcare and Pharmaceutics is working to implement and establish a "Network for the Emergency Preparedness and Response within the BSEC Region in the Field of Healthcare", to function in accordance with the International Health Regulation of the World Health Organization, with the aim to ensure the exchange of information on health threats, in real time among the participating BSEC Member States. The WG is also considering practical measures for implementation of the "Agreement on Cooperation in the Sphere of

Quality, Effectiveness and Safety Assurance of Medicines", which is aiming at: developing cooperation in combating the circulation of substandard, falsified and counterfeit medicines in the territories of the BSEC Member States; exchanging information on the facts of detection of substandard, falsified and counterfeit medicines- circulating in the territories of the BSEC Member States; exchanging experience of listing medicines for guaranteed medical care; exchanging information on national healthcare legislation; exchanging best practices in organizing laboratory control of medicines and experience, practices and methodologies during scientific-practical meetings, forums, conferences and seminars. The WG is also discussing the Memorandum of Understanding on Information Exchange and Cooperation in the Sphere of Quality Assurance of Medicines, signed so far by three BSEC Member States, namely the Republic of Armenia, the Republic of Moldova, and the Russian Federation.

b) The pharmaceutical industry in the European Union

24. The European Union (EU) is one of the largest markets in the world for pharmaceuticals and the pharmaceutical industry is a major contributor to the European economy. In 2019, the pharmaceutical sector contributed with 37 billion EUR to research and investment, 800 000 direct jobs and 110 billion EUR in trade surplus. The Member States of the EU are responsible for the definition and organization of their health policies and health systems. The EU has a supplementary and coordinating competence in public health policy, according to Article 168 of the Treaty of the Functioning of the European Union. The Union is responsible for the pharmaceutical legislation, and for various public health policies and it is its task to coordinate and complement national measures. It should also be noted that the EU has embraced the "Health in all Policy Areas" approach (HiAP), meaning synergy among its policies and dealing with health matters in a broad context. In addition, the European Medicines Agency plays a key role in harmonizing good manufacturing practice activities at the EU level, by coordinating inspections to confirm accordance with these standards.

25. A Pharmaceutical Strategy for Europe, published on 25 November 2020, aims to strengthen national health systems and ensure production of innovative and affordable medicines and maintain a competitive EU pharmaceutical industry, as part of the COVID-19 crisis response, since the COVID-19 pandemic has demonstrated a growing need for a better coordination across the EU Member States related to the management of health systems and health emergency response. The Pharmaceutical Strategy is based on 4 pillars that include: (1) ensuring access to affordable medicines for patients, and addressing unmet medical needs; (2) supporting competitiveness, innovation and sustainability of the EU's pharmaceutical industry and the development of high quality, safe, effective and greener medicines; (3) enhancing crisis preparedness and response mechanisms, diversified and secure supply chains, address medicines shortages; (4) ensuring a strong EU voice in the world, by promoting a high level of quality, efficacy and safety standards. In order to support the Strategy, the new 5.1 billion EUR EU4 Health programme was agreed upon, in December 2020 for the period 2021-2027.

26. The latest legislation in the EU recognizes the challenges of pharmaceutical residues in the environment and regards them as an emerging environmental issue. The European Parliament Resolution on Strategic Approach to Pharmaceuticals in the Environment (2020) identifies actions for stakeholders throughout the pharmaceutical life cycle, with an emphasis on sharing good practices, cooperating at international level, improving understanding of the risks, etc., in order to reduce the potentially harmful impact of pharmaceuticals on the environment.

c) Pharmaceutical industry in the Eurasian Economic Union (EAEU)

27. The pharmaceutical market of the EAEU countries is a promising market, due to the high demand for innovative and effective medical solutions and medicines, a set of government measures aimed at developing the pharmaceutical industry in the territory of the EAEU and reforming the health system to increase access to modern medical technologies and drugs.

28. According to the estimates of the Eurasian Economic Commission (EEC) in 2018, the value of pharmaceutical products manufactured within the EAEU Member States totaled 9243 million USD and the share of the EAEU in the global pharmaceutical market amounted to 2.6%. In the EEC Report "Development of Industrial Complexes of the EAEU Member States for the period January-December 2020", it is stated that the highest positive rate of growth in production volumes was recorded by the pharmaceutical industry (+ 23% growth). The pharmaceutical industry was the only manufacturing industry for which an increase in production volumes was recorded in all the EAEU Member States. In addition, the pharmaceutical products recorded the highest positive increase in exports (by 20.7%).

29. The Eurasian Economic Union has taken a number of measures aimed at establishing a common market of medicines and medical products within the Union, in accordance with Article 30 and Article 31 of the Treaty on the Eurasian Economic Union, dated 29 May 2014, the Agreement on Common Principles and Rules for Circulation of Medicines within the Eurasian Economic Union and the Agreement on Common Principles and Rules for Circulation of Medical Devices, signed on 23 December 2014, as well as the other acts of the EEC in the sphere of circulation of medicines. They include harmonization and unification of the requirements of national legislations; ensuring the unity of mandatory requirements for quality, efficiency and safety of medicines and medical products; adoption of common rules in the field of their circulation, etc. Unified registers of registered medicines and medical products are being formed, good development, research, manufacturing and distribution practices, as well as medicines and medical products safety control practices are being introduced. The common market started operating, however, the transition to the common pharmaceutical market of the EAEU has been made on a phased basis, to help entrepreneurs to better adjust to new conditions. It is envisaged that the rules for the production and registration of pharmaceuticals and medical products in the Union must be fully unified by 2025. It should also be underlined that the Eurasian Economic Commission has adopted the EAEU Pharmacopoeia, a set of requirements for the quality of pharmaceuticals which represents the basis for a unified method to assessing the quality of medicinal products in EAEU member states, upholding the Good Manufacturing Practice rules.

IV. PHARMACEUTICAL INDUSTRY IN THE BSEC MEMBER STATES

30. In recent years a number of important measures have been taken and reforms have been implemented in order to recover and develop the pharmaceutical industry in **the Republic of Azerbaijan.** The current legislation has been harmonized with international legal documents in this sphere. In order to improve the existing requirements for the production, transport and storage of medicines, as well as wholesale and retail trade in pharmaceutical products, the Board of the Ministry of Health of the Republic of Azerbaijan adopted the Decision "On Approval of Some Legal Acts Regulating Pharmaceutical Activity" (11 January 2018). The Annex 1 of the Document "Requirements for the Production, Transport and Storage of Medicines" defines the procedure for manufacturing practice.

31. Aiming to develop the pharmaceutical industry in line with international requirements, increase human capacity in this sphere and improve national legislation, the Analytical Centre of Expertise of the Ministry of Health works closely with international and regional organizations, among them the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) and the Pharmaceutical Inspection Cooperation Scheme (PIC/S). The Centre has become an observer in the ICH since June 2021. The Centre applied for PIC/S membership at the beginning of 2020 and was admitted to the initial phase of the membership process in August 2020.

32. The Law "On Amendments to the Law of the Republic of Azerbaijan "On Public Procurement" No75-VIQD of 1 May 2020 stimulates the production of medicines in the country. In accordance with the Decree of the President of the Republic of Azerbaijan "On Additional Measures to Stimulate Medicine Production" No1040 of 28 June 2020, medicines produced on the territory of the Republic of Azerbaijan are considered made domestically.

33. By the Presidential Order "On the Establishment of the Pirallahi Industrial Park" No 2336 of 14 September 2016, 30 hectares of land were leased in the Pirallahi area. The pharmaceutical plant was built by the Russian R-Farm company and operates since April 2020. Moreover, Diamed company specializing in the production of disposable medical syringes, opened syringe plant in Pirallahi Industrial Park. In addition, it is planned to build soon a new industrial complex Parla Pharmaceuticals.

34. The opening of the Centre for Nuclear Medicine at the National Oncology Centre on 25 April 2016 is the important step in the development of the domestic pharmaceutical industry. At present the Centre produces 14 types of radiopharmaceuticals.

35. The COVID-19 pandemic caused the increase in demand for personal protective equipment, as well as for disinfectants and antiseptics. To meet the needs, the number of manufacturers of medical antiseptic solutions was increased and in April 2020 in the Sumgait Chemical Industrial Park an enterprise for the production of medical masks was opened operated by Baku Textile Factory LLC.

36. The legal framework in **the Republic of Bulgaria** governing the sectoral policy related to medicinal products, guarantees high standards of quality and safety. The key principle on which the legislation is developed is that medicinal products may be placed on the market only after a marketing authorization is issued by the competent authorities. The requirements applied throughout the European Economic Area, of which Bulgaria constitutes a part, are harmonized around this principle. The Law on Medicinal Products in Human Medicine regulates the terms and conditions of all the aspects of pharmaceutical industry with the aim to establish the conditions that ensure the placing on the market of medicinal products that meet the requirements of quality, safety and efficacy. The Ministry of Health, the Bulgarian Drug Agency, the National Council on Prices and Reimbursement of Medicinal Products, the National Health Insurance Fund are the leading contributors to the implementation of the policy in the field of medicinal products. Good manufacturing practice standards are applied in Bulgaria and its pharmaceutical industry is GMP certified and, in terms of quality, is at the European level.

37. The coronavirus pandemic put a lot of pressure on the pharmaceutical system in Bulgaria. To address the shortage of essential medicinal products used in therapeutic schemes for the treatment of COVID-19 in Bulgaria, the export of these products was forbidden for a certain period of time. The Bulgarian pharmaceutical industry continues to invest significant financial

and scientific resources for the development of medicinal products in the fight against the pandemic caused by coronavirus infection. As of 21 June 2021, there are four permits in Bulgaria issued for the use of COVID-19 vaccines. Following the conditional authorization by the European Medicines Agency (EMA) of the medicinal product Veklury (Remdesivir) by Gilead Sciences, for the treatment of COVID-19 in adults and adolescents aged 12 years and older, with pneumonia, Bulgaria joined the EC Framework Agreement with the manufacturer (Company Gilead), which allowed the medicinal product to be provided on the territory of the country.

38. In 2020, the pharmaceutical market in Bulgaria grew by more than 7%, compared to the previous year, and the sales of medicines at pharmacy prices amounted to 2.06 billion EUR. The pharmacy market reached a value of 1.7 billion EUR and a growth of 5.8%. Pharmaceutical corporations from the top ten in Bulgaria, own about 40% of the pharmaceutical market in 2019, which is equal to 798 million EUR. Consolidation of the pharmacy network is expected, as Bulgaria currently occupies one of the top places in the EU, in terms of the number of pharmacies per capita – 1 pharmacy per 2,300 people.

39. Legislation of **the Hellenic Republic** regarding the production, distribution and use of medicinal products has been harmonized with the Directive 2001/83/EC of the European Parliament and the Council of the EU of 6 November 2001 on the Community code relating to medicinal products for human use. The legislation in the field of production and distribution of veterinary medicinal products has been harmonized with the Directive 2001/82/EC of the European Parliament and of the Council of the EU of 6 November 2001 on the Community code relating to veterinary medicinal products.

40. The requirements of the EU Good Manufacturing Practice (GMP) are followed regarding the manufacturing of pharmaceutical products in Greece and have been incorporated into the national legislation.

41. In Greece, at present, there are 78 authorized units, covering the production of sterile and non-sterile medicinal products intended for human and veterinary use. It should be noted that a high proportion of pharmaceutical products is produced under production contracts exclusively for export.

42. In the context of the COVID-19 pandemic and following the principle of National Procedural Autonomy, the production of “chloroquine” by a Greek Pharmaceutical Company has been approved, along with the production of “dexamethasone”.

43. The National Organization for Medicines (EOF) is a member of the Pharmaceutical Inspection Cooperation Scheme (PIC/S) and fully participates in developing, interpreting, and implementing the Good Manufacturing Practice standards.

44. In **the Republic of Moldova**, the field of the pharmaceutical industry is regulated by the Law on the Pharmaceutical Activity 1456/1993, which stipulates that medicines shall be produced by pharmaceutical enterprises and institutions, based on the license issued by the Medicines and Medical Devices Agency (MMDA). The Agency is empowered with regulatory and supervisory powers in the field of medicine and is subordinated to the Government. It evaluates the manufacturing conditions of medicines, provides supervision and control of the quality of medicines, carries out the expertise, approval and registration of medicines, and authorises the import of medicines. Only medicinal raw materials and auxiliary materials stipulated by the Pharmacopoeia or in the analytical and normative documentation, approved by the Ministry of Health, Labour and Social Protection, can be used to produce medicines. Also, the

pharmaceutical enterprises and institutions are duly responsible for the compliance of the produced medicines with the requirements of the analytical and normative documentation approved by the Ministry.

45. The pharmaceutical sector is an area subject to strict regulation at the governmental level, through the MMDA. Currently, about 6000 names of medicines are authorised in the Republic of Moldova. There are seven registered drug manufacturers which produce about 400 names of drugs from different pharmacotherapeutic groups, as well as nine economic agents that are licensed in the field of pharmaceutical activity, being located in pharmaceutical production enterprises, micro-production laboratories, whose products are remedies other than medicines.

46. The contribution of the pharmaceutical industry during the pandemic period in the Republic of Moldova consisted in the emergency production of drugs included in national clinical protocols and practical guidelines on the coronavirus infection COVID-19. In the same context, based on the provisions of Decision no. 41 of 13 January 2021 of the National Extraordinary Commission for Public Health, point 3 - Approval and authorisation of vaccines against COVID-19 -, the MMDA has implemented the procedure for authorisation of vaccines against COVID-19, included by WHO in the Emergency Use List (EUL), as well as the vaccines against COVID-19, whose dossiers have been submitted by the manufacturers, their quality, safety and efficacy being assessed in accordance with the legal provisions. All vaccines against COVID-19 are conditionally authorised for one-year period.

47. In order to improve the preparedness and response to crisis situations and to ensure the security of supply in the Republic of Moldova, the development of strategic production of domestic medicines and medical products are ensured, as well as the diversification of production and supply chains and stimulation of investments in the pharmaceutical industry.

48. In developing its policies in the pharmaceutical field, **Romania** is taking into consideration the Communication from the European Commission on effective, accessible and resilient health systems (COM/2014/0215). In order to ensure that patients have access to essential medicines whose current decrease in stocks in the country poses a risk to the health of the population, it was necessary to establish a legal framework to encourage the maintenance or introduction on the Romanian market of the medicinal products from the list of essential medicines recommended by the World Health Organisation.

49. According to the Rules on the calculation method and the approval procedure of the maximum prices of the medicinal products for human use, approved by the Order of the Minister of Health no.368/2017, the patients' access to essential medicines is encouraged by applying a calculation method based on the average of the last 3 prices from the states to compare for Romania. For all other medicines, the calculation method represents the minimum prices from the states to compare for Romania, in order to ensure the sustainability of the social health insurances system.

50. The National Agency for Medicines and Medical Devices of Romania (NAMMD) is the main competent authority under the Ministry of Health, with the mission to help protect and promote public health by evaluation of documentation for authorization in view of marketing safe and effective medicinal products for human use; surveillance of the safety of medicinal products for human use in therapeutic use by means of inspection and pharmacovigilance activities; ensuring access for the pharmaceutical industry, patients and healthcare professionals to useful and accurate information on medicinal products for human use authorized for marketing in Romania;

maintaining high level of performance and safety of medical devices in use by healthcare networks throughout the country; issuing specific technical procedures in the field of medical devices; ensuring institutional administrative effectiveness, efficiency and transparency of practices and procedures in use etc. The NAMMD actively participates in the evaluation of applications for authorisation through the European centralised procedure, which authorises innovative medicines in all the EU Member States, such as medicines developed for the treatment and prevention of Covid-19, as well as medicines for oncologic conditions.

51. The pharmaceutical industry in **the Russian Federation** has significant resources for innovative and technological development of production and increase of export to other countries. Competitive advantages are linked to research potential, developed military medicine and experience in the production of vaccines of various levels of complexity, which is a platform for innovation in producing new generation medicines. At present the state makes considerable efforts towards the innovative transformation of production of medicines and higher results in import substitution.

52. Based on the state program of the Russian Federation "Development of the Pharmaceutical and Medical Industries" approved by the Decree of the Government of the Russian Federation No. 305 dated 15 April 2014 (as amended on 31 March 2021), the domestic pharmaceutical and medical industry undergoes structuring using technological industrial clusters within the fundamentally new mechanism of scientific and industrial cooperation of enterprises, higher educational establishments and scientific organizations.

53. Thus, in the territories of some constituent entities of the Russian Federation, investment measures are carried out aiming at establishment of innovation centers for the development of medicines and medical devices, including research and educational bases, as well as technology transfer centers and pilot production facilities.

54. State procurement of medicines remains one of the drivers of growth through additional funding of national projects. The major part of this growth was achieved through the program "Fight against Oncological Diseases" and the federal project on heart diseases launched in 2020.

55. As of the end of 2020, the volume of the Russian pharmaceutical market increased by more than 10% and continues to show similar growth dynamics in the first half of 2021. The main stimuli for growth were products for the treatment and prevention of coronavirus infection caused by the SARS-CoV-2 virus.

56. It is also important to note the success of the Russian scientists in developing vaccines for the prevention of coronavirus infection and virus detection tests.

57. At present, import-substituting industries are being created, introducing new medical products and innovative medicines to the market. Additional measures are developed to support manufacturers of pharmaceutical substances. The regulatory legal framework regarding the state regulation of prices for medicines from vital and essential medicines list is being improved.

58. The Law on Medicines and Medical Devices of **the Republic of Serbia** regulates medicinal products for human use in the Republic of Serbia. The medicines authorized for use must meet the quality, safety, and effectiveness conditions. They are subject to regular and for-cause quality control and are included in the national pharmacovigilance system. The Government of the Republic of Serbia's Activity Plan 2021 envisages a new law on medicines that will be fully harmonized with the EU acquis, ensuring the free movement of goods on the Serbian market and

protection of public health, as well as the full harmonization of national legislation with the EU regulations and directives governing the entire life cycle of the medicine.

59. The Medical Device Law was adopted on 1 December 2017 and has entered into force on 2 December 2018, after 17 by-laws, necessary for the full application of the Law, were adopted. The Law lays down the conditions for the manufacture and marketing of medical devices, their placement on the market and their use in the Republic of Serbia, clinical research, vigilance, their monitoring on the market, technical assessment, conformity assessment, advertising, labelling and supervision, as well as other relevant issues. Under the Law, only medical devices that have gone through the conformity assessment procedure and carry the "SE" symbol (approved by the notified EU body) or the Serbian conformity symbol (approved by the nominated Serbian body) may be marketed and used in the Republic of Serbia.

60. The Ministry of Health issues authorisations for the wholesale and retail of medical devices. The Serbian Chamber of Commerce keeps the registers of wholesalers and retailers of medical devices that are available to the public. The Serbian Medicines and Medical Devices Agency (ALIMS) issues market authorisations for medicines, and the information is available to the public. The Agency issues authorisations in line with the Directive 2001/20 EC and the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) Guidelines. The ALIMS is responsible for the marketing authorisation procedure, the renewal and amendments to these authorisations, as well as the registration of medical devices and traditional herbal and homoeopathic medicines in the Register of Medical Devices. All these procedures are in line with the highest international standards in this field.

61. The Serbian pharmaceutical market is dynamic and constantly growing. The total trade in medicines in Serbia in 2020 amounted to approximately 155 billion RSD (approximately 1,32 billion EUR). The pharmaceutical industry has made a tremendous contribution to the suppression and prevention of the COVID-19 pandemic, by accelerating vaccine development, making other therapies available and, both at the very beginning and later, by providing a range of medical devices, from protective face masks to ventilators.

62. The Pharmaceutical and Medical Preparations Law No. 1262 of **the Republic of Turkey**, published in the Official Gazette and dated 26 May 1928, regulates general principles of the medical products for human use, including vaccines, and empowers the Ministry of Health as the regulatory authority. In addition, "The Regulation on Pharmaceutical and Medical Preparation Manufacturers" was published in the Official Gazette No. 18562, on 1 November 1984 and has been in force since 1985. With the start of Turkey's official accession negotiations to the European Union on 3 October 2005, the national legislation on pharmaceuticals has been aligned with many European Union directives. "The Regulation on Changes in Medicinal Products for Human Use which have been Registered or for which Registration Applications have been made" that regulates all registration procedures, has been substantially aligned with the EU Directive No. 2001/83/EC and was published in the Official Gazette No. 25705, on 19 January 2005. The relevant national legislation in the field of pharmacovigilance, clinical research, medical devices and cosmetic products is within the area of responsibility of the Turkish Medicines and Medical Devices Agency (TMMDA) and has also been aligned with the respective European Union directives. The TMMDA has been a member of Pharmaceutical Inspection Cooperation Scheme (PIC/S) since 1 January 2018, as well as a full member of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use since 27 May 2020. With this membership, it has been acknowledged that the medicinal products

licensed in the country, the conducted clinical studies and the pharmacovigilance activities carried out meet the international standards.

63. In 2020, the Turkish pharmaceutical market reached a sales value of 50.39 billion TL (approximately 5 billion EUR) and the sales volume increased to 2.27 billion boxes. Prioritization of domestic production with the health transformation program; inclusion of the pharmaceutical industry among the strategic sectors such as defense and energy industry; new incentive system and Turkey's high export potential are among the factors that led the Republic of Turkey to become one of the investment centers in the field of pharmaceuticals and medical devices for domestic and foreign investors. The important works are currently carried out in cooperation with the relevant institutions on the supporting mechanisms that will enable Turkey to become international and regional management and joint service center in the field of pharmaceuticals and medical devices. This issue has been highlighted in the major policy documents and in the Development Plans with the aim to switch to a production structure that can produce high value-added products, offer products and services to global markets, and meet a larger part of domestic drug and medical device needs.

64. The Health Industries Steering Committee was established pursuant to the Prime Ministry Circular No. 2015/19, published in the Official Gazette dated 23 December 2015 and numbered 29571, in line with the Action Plan of the Structural Transformation Program in the Health Industries of the Tenth Development Plan (2014-2018). The aim is to evaluate and coordinate issues such as increasing investment, production and exports, pricing for the development of technology, reimbursement, registration, public procurement, public support, trade policies, health technology policies, data management and dialogue with the private sector, in the field of health industries with a holistic approach.

65. Related to the fight against COVID-19 pandemic, Turkey reviewed the production plans, in coordination with the pharmaceutical companies and thoroughly planned imports and exports of the drugs used for the treatment of COVID-19. In addition, alternative supply hubs for raw materials and auxiliary materials were determined regionally and the pharmaceutical supply chain was constantly monitored in order to use the existing stocks efficiently.

66. The Law of **Ukraine** "On Medicinal Products" regulates legal relations associated with the creation, registration, manufacture, quality control and realization of medicines, including medicines made from human blood and plasma of blood (blood medicines), conversion, transportation, storage and distribution of the components of blood used for production of medicines. It determines the rights and obligations of the companies, organizations and citizens, and also powers in this sphere of executive bodies and officials.

67. Ukraine has its own production, which is reaching the global quality level, with a developed network of distributors and pharmacies. The volume of the pharmaceutical market continuously grows. The main task is to organize the stable operation of enterprises in the sphere of circulation of pharmaceuticals. Supply of medications for the population and their availability constitute the main component of the state healthcare policy, which aims at establishing patient-centered system. Reform of the national system of admission of pharmaceuticals to the Ukrainian market will allow avoiding duplication of functions of the respective bodies, simplification of the decision-making process and the introduction of the transparency principles in the pharmaceutical sector of Ukraine.

68. The state policy in the sphere of drug circulation is directed to promotion of scientific research, new technologies, development of highly efficient and safe medicines, supply of quality medicines in the necessary range through implementation of respective state programs, priority financing, preferential loans, and tax incentives. According to the strategic documents, the goal is to achieve better healthcare indicators, to supply efficient and safe pharmaceuticals for the population of Ukraine and ensure their rational use.

69. Leading Ukrainian companies have carried out technical modernization and applied modern methods of developing and promoting pharmaceutical products. The production capacity of Ukrainian enterprises complies with the rules and regulations stipulated in the Good Manufacturing Practice, as well as other international standards. With the aim to ensure identification of pharmaceutical products with special 2D barcodes and to revise the legal acts of the Cabinet of Ministers of Ukraine regarding prevention of counterfeiting of pharmaceutical products, a Working Group has been set up in the Ministry of Health of Ukraine, which works on the issues of marking the medication packages with 2D barcodes. The Ministry of Health is developing a strategy for the phased introduction of electronic prescriptions.

70. The national pharmaceutical industry moves slowly but steadily towards increasing export and exploring new markets. Some companies actively enter the EU market. Timely modernization, cooperation with international partners, attention to quality and availability, active entry to the international market helped the pharmaceutical companies to become successful. In the beginning of the current year, 120 industrial pharmaceutical manufacturers and 193 licensors involved in import of medicinal products (excluding Active Pharmaceutical Ingredients) were registered in Ukraine.

V. CONCLUSION

71. The pharmaceutical sector plays an important role in the well-being of society. Global pharmaceutical industry occupies an important place in the world economy, characterized by high investment attractiveness. The pharmaceutical industry contributes to employment, trade, research and development. It should be noted that the pharmaceutical industry remains a key factor in the development of the economy of many countries and is one of the most knowledge-based sectors of the economy, which is associated with high-tech production processes. This sector of the economy is subject to strict government regulation in order to pursue an effective and sustainable health policy and ensure the effectiveness, safety and quality of medicinal products.

72. The strategic development of the pharmaceutical industry is influenced by demographic and epidemiological trends. Typical diseases determine the direction of research and development and investment activity. Medical discoveries provide people with a better quality of life and greater productivity, which in general, has a beneficial effect on society. Remaining a socially significant area, the pharmaceutical industry is dependent on regulatory decisions and the effectiveness of the management of research and development processes and is an important component of drug safety. In 2020, the global pharmaceutical market demonstrated an active growth, in the context of the coronavirus pandemic. New challenges bring new opportunities, and pharmaceutical industry adapts quickly and flexibly to new challenges.

73. From the first steps of its development, the pharmaceutical industry has been largely focused on creating innovative products and expanding the medical science. This industry continues its experiments with different paradigms, revising the existing methodology, with the aim to help

fight diseases and achieve the global healthcare objectives. Sound pharmaceutical policies are fundamental to the well-functioning healthcare systems. Pharmaceutical industry plays an important role in ensuring access to new medicines and in supporting the overall healthcare structure. Success in this sector requires joint efforts and the cooperation of all the involved parties.

74. The BSEC Member States work closely to increase the cooperation for increasing peoples' awareness and reaching rational use of medicines, ensuring fast and safe access of medicines to their citizens. Compliance with international quality and safety standards and good manufacturing and distribution practices should be further implemented and enhanced in the national legislation, as well as the cooperation with the WHO and other regulating autorities. National health and strengthening of the healthcare systems are priorities in the states everywhere in the world, but the resources allocated for these purposes vary considerably from country to country. Building strong health systems prepared for emergence situations requires long-term strategic planning and management, political accountability and upgraded national legislation.

75. The possible environmental impacts of pharmaceutical substances into the environment are to be taken into account while focusing on public health needs. This requires the involvement of all relevant stakeholders along the entire process, including the BSEC Member State competent authorities, the pharmaceutical industry, medical professionals, patients, etc., with the mutual aim of promoting safe medicines, healthier environment and strong pharmaceutical economy. In addition, it is important to stimulate "green pharmacy" that acknowledges the potential for creating new medicines that are less damaging for the environment.

76. Promotion of cooperation in the field of pharmaceutical sector among the BSEC Member Countries facilitates harmonization of legislation, coordination of efforts in solving common problems and exchange of experience. Mutually beneficial cooperation can be developed by exchanging of information on pharmaceutical legislation, in order to improve and harmonize the legal basis; conclusion of bilateral, as well as multilateral agreements in the field of pharmaceutical sectors among the BSEC Member Countries; transfer of expertise, know-how and technology; exchanging visits among the representatives of ministries of health, pharmaceutical companies, universities, medical establishments, with a view to enrich their experience, etc. For ensuring health and well-being of the BSEC Member States' citizens, it is necessary to deepen the cooperation in combating the circulation of substandard, falsified and counterfeit medicines in the territories of the BSEC Member States.

77. Upon the initiative of the Russian Federation, the Organization of the Black Sea Economic Cooperation has been considering for several years the Draft Agreement on Cooperation in the Field of Sanitary Protection of the Territories of the BSEC Member States. It is necessary to return to this document and accelerate its adoption in order to improve cooperation in the field of health care and to ensure coordination of the Black Sea region states for epidemic prevention and sanitation measures as well as sanitary protection.

78. The pandemic crisis has proved the necessity of a more efficient systemic approach to emergency preparedness and enhanced regional cooperation in its management. The BSEC Member States should rethink trade barriers and impediments to avoid unnecessary disruptions in the production and distribution of essential goods, which is of outmost importance in times of need. It is also important to enhance the cooperation in the field of development, production and distribution of vaccines and antiviral drugs.

79. Today, people live longer and healthier lives than previous generations because of the pharmaceutical innovations and progress in modern medicine. Addressing the complex healthcare challenges, including COVID-19, calls for a long-term commitment of governments, civil society, and the private sector. Much needs to be done as the way forward requires a constant re-evaluation of the approaches on how to maximize the positive impact of a research-based pharmaceutical industry on health and prosperity for all the countries and the peoples taking advantages of major medical discoveries.