

PARLIAMENTARY ASSEMBLY OF THE BLACK SEA ECONOMIC COOPERATION PABSEC

INTERNATIONAL SECRETARIAT

Doc.: GA58/EC57/REC 182 /21

RECOMMENDATION 182 /2021*

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

1. The Parliamentary Assembly of the Black Sea Economic Cooperation (PABSEC) underlines the significant role of pharmaceutical industry in improving the health and quality of life of the population throughout the world and acknowledges that the success of this sector requires more targeted action, joint coordinated efforts and cooperation of all the stakeholders, at national and international levels. As one of the most innovative and knowledge-based sectors of the global economy, the pharmaceutical industry has a key function to generate new medicines and vaccines for the prevention and treatment of diseases, through the development of medical biotechnology, based on fundamental, experimental and clinical research and adapting the existing methods to the global health objectives. Being an industry with strong investment potential, it contributes to economic development, employment and trade growth.

2. The PABSEC recognizes the importance of increasing domestic pharmaceutical capacities and the efficiency of a systematic approach to healthcare emergency preparedness of the pharmaceutical industry in the BSEC Member States, as well as strengthening regional cooperation. Sound pharmaceutical policies are fundamental to the well-functioning healthcare systems. Improving access to medicines, preventing shortages and supporting national action and international efforts to combat the spread of substandard and counterfeit medicines, are essential to protect and improve public health.

^{*}Assembly's debate on 22 November 2021 (see Doc.: GA58/EC57/REP/21, Report of the Economic, Commercial and Financial Affairs Committee "Cooperation in the Field of the Pharmaceutical Industry in the BSEC Member States", discussed online on 22 September 2021; Rapporteur: Mr. Nikolay Kolomeytsev, Member of the Committee- the Russian Federation)

Text adopted at the General Assembly, on 22 November 2021 at online meeting.

3. The PABSEC recognizes the importance of the achievement of the United Nations Sustainable Development Goals (SDG) "Transforming our World: the 2030 Agenda for Sustainable Development" and extends its full support to the SDG 3 on ensuring healthy lives and promoting well-being for all, aiming at transforming health systems and adapting them to the challenges of the 21st century.

4. The PABSEC states its concern over the fact that after one year from the outbreak of the COVID-19 pandemic, the world still faces human tragedy and a health emergency. The pandemic has become a real challenge for the states in all the spheres, including the pharmaceutical industry. The social and economic consequences of the pandemic are colossal and continue to grow. The pandemic has demonstrated the need to transform domestic health systems and the pharmaceutical industry and ensure preparedness and response against the pandemic. In this regard, it is necessary to show determination in taking the necessary decisions and actions, in a spirit of unity and solidarity, in the light of the urgent need to save lives and build a better future.

5. The PABSEC welcomes the activities of the Organization of the Black Sea Economic Cooperation (BSEC) and its bodies, within the framework of the "BSEC Economic Agenda: Towards an Enhanced BSEC Partnership" (2012), which explicitly refers to strengthening the cooperation in the spheres of healthcare and pharmaceutics. The Assembly also welcomes the BSEC Ministerial Declarations in this field, which stresses the importance of the cooperation among the Member States in the pharmaceutical and medical industries. The Assembly compliments the BSEC's initiative to establish a "Network for the Emergency Preparedness and Response within the BSEC Region in the Field of Healthcare", supports the BSEC efforts to implement the "Agreement on Cooperation in the Sphere of Quality, Effectiveness and Safety Assurance of Medicines" and to sign the Memorandum of Understanding on Information Exchange and Cooperation in the Sphere of Quality Assurance of Medicines. The PABSEC also supports developing cooperation in the field of sanitary protection, according to the national legislation, and encourages the BSEC's efforts to finalize the "Agreement on Cooperation in the Field of Sanitary Protection of the Territories of the BSEC Member States".

6. The PABSEC appreciates the active work of the authorities of the BSEC Member States in improving the legislation, policies, strategies and plans in the field of pharmaceutical industry and notes that the national approaches may differ from country to country. The priorities in this regard should be aimed at ensuring effectiveness, quality and safety of medicinal products, as well as the practical implementation of the accepted international norms and standards.

7. The PABSEC recognizes that in the process of increasing the capacity of the pharmaceutical industry, it is important to take into account potential environmental risk factors caused by the pharmaceutical substances and calls on the BSEC Member States to take targeted and coordinated measures to ensure the environmentally sound regulation of pharmaceutical production and to achieve relevant goals and objectives in the field of sustainable development.

8. The Assembly attaches a special importance to global partnership at different levels and regards the enhancement of the collaboration with international and regional specialized organizations, including the World Health Organization (WHO), the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) and the Pharmaceutical Inspection Cooperation Scheme (PIC/S), as a useful mechanism for improving the well-being of peoples in the Black Sea region.

9. Therefore, the Assembly recommends that the Parliaments and Governments of the BSEC Member States:

i. *exchange* information on national pharmaceutical legislation and stimulate cooperation among competent authorities;

ii. *update* national legislation and regulations, to conform with the global norms and standards set by the WHO and other relevant regulating authorities in the areas of medicines development, production, distribution, inspection and quality control;

iii. *formulate* healthcare strategies and effective mechanisms aimed at achieving the SDGs, particularly Goal 3 on health and well-being;

iv. *promote* further cooperation among the BSEC Member States in the field of pharmaceutical industry by concluding bilateral or multilateral agreements, as well as protocols of cooperation and memorandums of understanding between national regulatory authorities;

v. *facilitate* the dialogue among the stakeholders in the pharmaceuticals manufacturing value chain, public authorities, medical experts, patients, and the research community, in order to strengthen the resilience of the domestic pharmaceutical supply chains and ensure the security of the supply of medicines;

vi. *encourage* boosting domestic pharmaceutical production capacities, to eliminate the future potentional shortages, especially of essential pharmaceutical products and medical personal protective equipment;

vii. *intensify* cooperation in combating the circulation of substandard, falsified and counterfeit medicines in the territories of the BSEC Member States, and exchange information on the facts of detection of such goods;

viii. *stimulate* "green pharmacy", to create new drugs that are less harmful to the environment, taking into account the possible environmental impact of the pharmaceutical substances and the needs of public health and environmental risks;

ix. *enhance* the cooperation in the field of development, production and distribution of vaccines, diagnostic tools and antiviral drugs, including the transfer of expertise, know-how and technology;

x. *exchange* visits among the representatives of ministries of health, pharmaceutical companies, universities, medical establishments, in order to share best practices, advanced experience and methodologies;

xi. *promote* enhancement of cooperation in the field of pharmaceutical sciences, with special emphasis on the exchange of young scientists and organisation of their internships in leading scientific laboratories and research centers, with the aim to improve qualifications and gain experience in the field of the latest achievments of modern pharmaceutical industry;

xii. *set forth* investment strategies in order to attract domestic and foreign direct investment in the pharmaceutical industry, for the development and implementation of new effective technologies, for the prevention, diagnostics and treatment of diseases within the healthcare system;

xiii. *facilitate* export of domestic pharmaceutical products to the world markets;

xiv. *encourage* involvement of public and private institutions in the form of public-private partnerships, in the elaboration and implementation of scientific programs in priority areas of the pharmaceutical industry, to maintain public health;

xv. *provide* legislative support to pharmaceutical manufacturers and researchers, for the development and production of high-quality medicines, improving the quality level of healthcare systems;

xvi. *stimulate* research and innovation, to introduce cutting-edge technologies and medical approaches and promote the strengthening of national research and development centres;

xvii. *mobilize* financial resources for developing a long-term perspective research in the pharmaceutical sphere;

xviii. *take necessary measures* for avoiding trade impediments to prevent disruptions in the production and distribution of essential medicines;

xix. *deepen* the cooperation in the field of sanitary protection and ensure coordination of states' anti-epidemic and sanitary-hygienic measures;

xx. *promote* implementation of the strategic objectives in the pharmaceutical sector, stipulated in the BSEC policy documents;

xxi. *provide* the necessary support to the activities of the BSEC Working Group on Healthcare and Pharmaceutics and the implementation of the BSEC Action Plan elaborated by this Working Group.

10. The Assembly invites the BSEC Council of Ministers of Foreign Affairs to consider this Recommendation.