

AMERICAN CHAMBER OF COMMERCE IN MOLDOVA

COOPERATION FOR A COMPETITIVE BUSINESS ENVIRONMENT

RECOMMENDATION PACKAGE



ABOUT AMCHAM MOLDOVA

Mission

To promote US, foreign, and local investments in Moldova and to work with the Moldovan government and business leaders to foster a more favorable business climate in Moldova.

AmCham Moldova is a non-governmental, non-profit, non-political organization, belonging to a large international network of similar organizations present in over 100 countries of the world.

The members of AmCham Moldova are about **130 private companies** with **capital from over 20 countries**, including companies with US capital and domestic capital, **operating in different industries** of the national economy, contributing significantly to the state budget and **creating thousands of jobs** in the country.

AmCham Moldova
fighting for your business

Foreword

The American Chamber of Commerce in Moldova, historically, comprises a wide range of companies representing multiple industries, that come from different jurisdictions. This allows AmCham to gather data on the best business regulatory practices worldwide, to process the information in the local context, and to afterward come up with recommendations to address the challenges of the business community.

Thus, for 12 years, in a consistent and constructive manner, we are putting forward proposals in multiple packages of legislative recommendations, making them available to Governments, in order to serve our mission - that of fostering a favorable climate for entrepreneurial activity through an open dialogue and a close cooperation with the Moldovan authorities.

AmCham Moldova's advocacy agenda is shaped by the concerns and needs of our member companies, strongly correlated to the EU-Moldova Association Agreement Implementation Agenda, resulting in more than 50 position papers issued yearly.

We strongly believe that Deep and Comprehensive Free Trade Area is the only viable solution that, if implemented, will move towards improving ease of doing business in Moldova and will serve as a powerful tool to promote Moldova as an investment destination.

The "Cooperation for a competitive business environment" recommendation package represents a compendium of major priorities for reform in business that, if addressed, will boost Moldovan investment climate ranking, therefore will impulse the attraction and retention of foreign direct investments in the country.

At the same time, we should acknowledge the existence of a series of **social fundamentals** like rule of law, equity of justice, predictability of legal framework, reliable infrastructure, and a vibrant labor, and consumer market. The dysfunctionalities of these elements minimize the efforts targeted at reforming the business environment.

The "**Cooperation for a competitive business environment**" reaffirms AmCham's commitment to constructively contribute to improving the business climate in Moldova, boost foreign direct investment, support the reforms aimed at ensuring our progress on the association agenda with the EU, and, ultimately, ensure sustainable economic growth.

Traian Nechifor, President, AmCham Moldova

AMCHAM MEMBERS

7Reasons
Abbott
ACI Partners
Agro Mester HD
Autodoctor
Aventus Finance
Avon Moldova
Baker Tilly
Banca Comercială Română Chișinău
BASS Systems
Bayer
BDO Moldova
BDR Associates - Strategic
Communication
Bemol Retail
Berlin-Chemie / Menarini
Best Western Plus Flowers Hotel
BPay
British American Tobacco - Moldova
Brodsky Uskov Looper Reed &
Partners
BT Leasing MD
Business Class
CA Donaris Vienna Insurance Group
Carlsberg
CashPoint
Chemonics International
Cobzac & Partners
Coca-Cola Hellenic Moldova
Comertbank
Credit Rapid
DAAC Hermes
Danube Logistics, GIFP
DAS Solutions
Deloitte
DHL Moldova
Dita Estfarm
DRA Draexlmaier Automotive
Easy Credit
Edenred
Efes Vitanta Moldova Brewery
Efrim, Roșca & Associates BAA
Electra Norte Molwind
Elicio NV
Ellation
Europlast-Chisinau
Express Leasing & Microcredit
EY Moldova
Fagura
FinComBank
Forward International
Gebauer & Griller Cables and
Wires
Gladei & Partners
Glass Container Company
Grant Thornton
Grawe Carat Asigurari
Herbalife Nutrition
HR-Consulting
Imunotehnomed
Incaso
Indigo Ogilvy
Indra Sisteme
Infodebit Credit Report
Iute Credit
JT International Trading
Kozlovna
KPMG Moldova

AMCHAM MEMBERS

KVG LLC
Lafarge Ciment (Moldova) S.A.
Le Bridge Corporation Limited
Lear Corporation
MAIB
MAIB-Leasing
Mary Kay Moldova
Mastercard
Mentor Express
Metro Cash & Carry Moldova
Microinvest
Mikro Kapital
Mixbook
Moldcell
Molsalvia
Monicol
Moore Stephens KSC
MT International Group
NCH Advisors INC.
Nefis
Nestle Products Export Corporation
Novo Nordisk A/S
Orange Moldova
Orbico Moldova
Orhei-Vit
Oriflame International
P.A.A. Tax, Legal, Accounting
Paynet Services
Pedersen & Partners
Pegas
Petrom Moldova
Philip Morris Sales & Marketing
Politrans
PricewaterhouseCoopers
Moldova
Prime Capital
Primo Contatto Multilingual
Contact Center
Prograin Organic
QIWI Moldova
Red Union Fenosa
Rihpangalfarma
Ritlabs
Rogob
Rompetrol Moldova
Rural Finance Corporation
SANOFI
Schoenherr Attorneys at Law
Sebo
Sixt Rent a Car
Sudzucker Moldova
Tacit Knowledge
Takeda Pharmaceutical
Tetis International CO
Total Leasing & Finance
Trans Oil Group of Companies
Trigor AVD
Turcan Cazac Law Firm
Up Moldova
Valah
Vernon David
Victoriabank
Visa
Xerox

LATEST DETERMINANTS OF INCREASED COMPETITIVENESS

- Attractive taxation regime
- Moldova – EU Association Agreement
- Tailored business ecosystems (Free Economic Zones; IT Parks)
- Free trade agreements with major regional economic powers
- Liberalization of business activities
- Legislative amendments to support flexible working schemes



EIGHT PRIORITY RECOMMENDATIONS

- I. Do not Compromise on Fundamentals**
- II. Enhance Investment-Friendly Business Environment**
- III. Guarantee a Competitive and Predictable Tax Regime**
- IV. Ensure a Competitive Labor Regulation Framework**
- V. Streamline the Cross-border Trade and Access to Market**
- VI. Focus on Industrial Policy**
- VII. Enhance the Financial Services Usage**
- VIII. Advance on Digital Transformation**

PRIORITY I: Do not Compromise on Fundamentals

Any effort made to reform the business environment will be compromised and minimized in the absence of fundamental premises such as:

Combating corruption at all levels to create a fair competition environment for all participants

The strong consensus among the private sector is that corruption remains to be a widespread phenomenon infiltrated in all public authorities delivering services to business.

102nd place on the incidence of corruption (2017 Global Competitiveness Index, WEF)

It shatters the rule of law and thus hampers the effective application of Moldovan laws, and fails to protect the legitimate rights of entrepreneurs. It also destroys the level playing field both within and across industries by inequitable application of the law to all companies.

6% of businesses feel treated equally by the law (2018 Cost of Doing Business, World Bank)

Ensuring real and effective judicial reform to guarantee fair justice

Aside from all of the financial assistance and expertise provided by the EU and the USA, the justice sector still remains to be weak, within which court bribery is almost an ordinary practice. The court system frequently makes decisions in contradiction to Moldovan law, a situation that is illustrated by Moldova's poor history in the European Court of Human Rights. The level of business trust in the Moldovan court system is also low as foreign investors feel more harassed than protected by the local judiciary.

76% of businesses are unsatisfied by the quality of justice (Confidence in the Justice System of the Republic of Moldova, LRCM)

Reducing outflow of human capital through economic and social policies that encourage citizens to live, work and invest in Moldova

The consistent emigration trend mixed with a falling birth rate creates a unique challenge on the near-term ability to find skilled employees.

The issue is amplified within the industries where specific background and technical skills are required. The problem is even more acute in rural parts of the country. A continuous effort should be deployed to improve the working and living environment, so that there are incentives for skilled and well-qualified Moldovan citizens to stay in the country and for Moldovans living and working abroad to return home.

Developing a reliable infrastructure

All above listed deficiencies are amplified by inadequate physical infrastructure. Poor roads and difficult access to public utilities are being identified across a range of industries, especially those involved in manufacturing and cross-border trade.

Although the density of roads is considered acceptable, their quality is still poor, resulting in significant transport repair costs and delays in deliveries.

Furthermore, a deficient customs' posts infrastructure is also considered as an obstacle for streamlining external trade. The enabling of the working energy market has the potential to boost foreign and local investments in the industry and thus reduce Moldova's electricity & gas supply risks.

The poor state of roads implies additional costs for users amounting to approximately \$213 million annually (UNCTAD "Investment Policy Review")

Achieving Energy Security by Transition to Clean, Safe and Affordable Energy

Under the ongoing geopolitical situation and a dependence of the country on import of energy, energy security issues remain to be imperative. In this regard, Moldova should align its priorities on this dimension to the EU ones, namely providing access to secure, affordable and climate friendly energy facilitate the transition away from fossil fuels towards cleaner energy.

The enabling of the working energy market has the potential to boost foreign and local investments in the industry and thus reduce Moldova's electricity & gas supply risks.

PRIORITY II: Enhance Investment-friendly Business Environment

Guarantee the predictability of the long-term and short-term business regulatory regimes

The Deep and Comprehensive Dimension of the Free Trade Agreement between Moldova and EU is and must remain to be the most reliable guarantor of a better and more predictable policy environment. Therefore, Moldova should implement an outward looking approach understanding competition for investments at global level, thus to provide industry with a well-functioning and predictable legislative framework.

Moldova still presents tremendous challenges to investors hoping that a business model will enjoy some level of regulatory predictability, as an entrepreneur when building its business model, including such features as product approval, cost features, distribution channel and tax treatment should be sure that it can be built on a relatively stable business environment.

- To ensure predictability of the regulatory environment so businesses can focus on delivering the best products and services to their customers;
- To provide reasonable time to adjust the business models to the upcoming regulations.

Dialogue with the private sector to align public and private priorities for development

It is crucial that any decision affecting entrepreneurial activity be reviewed in terms of regulatory impact and communicated to business entities promptly.

- To improve transparency of the decision-making process by not making or amending laws, regulations, decisions, orders, etc. unless they have passed through a robust consultative process involving the private sector and civil society, and by not substantially changing them after the consultative process;
- To streamline feedback to the private sector by clearly explaining why private sector proposals and recommendations, developed and delivered in good faith, are not accepted;
- To actively and routinely solicit input from the private sector about their needs on issues affecting the business climate; and on what sectors of the Moldovan economy should be considered as drivers of future economic growth and employment;
- To maintain and further develop the existing platforms that proved to be efficient in hosting important public-private dialogue, such as:

- Economic Council to the Prime Minister of the Republic of Moldova
- National Working Group on Regulation of Entrepreneurial Activity
- Advisory Committees under various Government agencies
- Councils of Dispute Resolution
- To focus on building ex-ante compliance mechanisms preventing anti-competitive practices than on their post-factum fighting;
- To continue the capacity building of the Competition Council in terms of human and financial resources, so that the institution could perform its competencies independently and efficiently.

Competition legislation

The risks implied by non-compliance to competition requirements may be very high. Thus, a non-compliant company may be subject to severe fines, the payment of damages incurred by their competitors or customers due to anti-competitive behavior, or may be exposed to contractual risk, as most anti-competitive agreements are illegal and therefore unenforceable. Also, not to be ignored is the reputation risk which usually surrounds any major competition case.

Therefore, more and more businesses seek to elaborate and implement internal policies on competition compliance, that would enable them to duly organize their business in compliance to competition rules, as well as to react in a due manner in

case of any potentially harmful behavior from a competition point of view.

- To focus on building ex-ante compliance mechanisms preventing anti-competitive practices than on their post-factum fighting;
- To continue the capacity building of the Competition Council in terms of human and financial resources, so that the institution could perform its competencies independently and efficiently.

Permissive acts

The existence of cumbersome, and, at times, unpredictable and nontransparent procedures of getting permits, authorizations, licenses, and other documents required by Moldovan authorities for an enterprise to do business, imposes additional pressure on businesses.

- To eliminate barriers to doing business and daily bureaucratic hassles so that businesses can operate freely and remain focused on activities that create value for Moldova;
- To improve and simplify the legal framework governing the issuance of permissive documents, by militating for one-stop shop procedures, the digitalization of public services, and the elimination of redundant or duplicative authorizations.

PRIORITY III: Provide a Competitive and Predictable Tax Regime

In recent years business has experienced a significant number of changes in tax and customs laws, which have significantly increased the uncertainty in long-term business activity and imposed frequent adjustment and adaptation of business plans.

Moreover, it is well known that the stability of fiscal and customs policy is a key factor in attracting investment in the economy.

- To ensure predictability of the tax system by timely consulting the proposed Tax Policy with relevant stakeholders and correlating it with the Medium-Term Budget Framework;
- To modernize the tax legislation by inspiring from the best international practices, but also taking into account the priorities assumed within the DCFTA (CIT & VAT);
- To revise the current taxation mechanisms of the social and health insurance contributions;
- To review currently applied tax regimes for certain categories of business taxpayers (i.e. “patenta de întreprinzător”), bringing it in line with the best international practices;
- To ensure the functionality of new tax administration facilities, such as the advanced tax ruling, the dispute resolution council, the digitization of services;
- To guarantee transparent, risk-based approach of tax inspections;
- To relaunch the discussions on the Double Taxation Avoidance Agreement between the United States of America and Moldova.

PRIORITY IV: Ensure a Competitive Labor Regulation Framework

AmCham members continue to signal the need to modernize labor legislation, reduce the bureaucratic burden imposed on employers, and transpose best international practices.

The main problems include the scarcity of qualified human resources on the national labor market linked to growing migration trends and the slow adaptability of education programs available in state institutions.

- To reform the education system to align it to the needs of the real economy – present and future – so that it produces graduates that meet the real needs of the private and public sectors in Moldova;
- To modernize the Labor Code, and related regulations to create conditions that maximize labor productivity, while protecting essential workers' rights and growth of high-employment sectors;

- To further simplify immigration rules to more easily permit qualified blue- and white-collar workers and their families to live and work in Moldova when they fill jobs for which shortages exist within the local labor market;
- To modernize regulations for employees' outsourcing;
- To stimulate provision of benefits to employees by offering related tax incentives to companies that offer such benefits (i.e.: meal tickets, etc);

PRIORITY V: Streamline the cross-border trade and access to market

International trade policy

- To advance on negotiations with China on a free trade agreement;
- To pursue new opportunities to sign free trade agreements with other countries;
- To ensure a level playing field between the US originated products and goods of preferential origin;
- To tackle the issue on recent introduction of antidumping duty on Moldovan cement imports to Ukraine.

Customs procedures

Although export customs procedures are considered to be more openly facilitated, companies experience delays and over-bureaucratization in the issuance process of certificates of origin. AEO status is not fully operational due to the lack of designated lines, and proper management of the trucks' queues.

Among the main issues that importers complain about is the practice of applying an unjustified increase in customs value to imported goods by using reference values. This particularly concerns the invoice prices of imported goods and transportation costs. Non-acceptance of certificates of origin is another significant procedural obstacle related to the import of goods. Lack of proper regulations

or customs terminals has a significant impact on costs related to the customs clearance procedure.

- To continue the digitization of customs procedures, thus ensuring a streamlined clearance of goods and reduced interaction between customs representatives and businesses;
- To conceptually review the customs infringements and related sanctions system;
- To eliminate discretion and increase transparency within the assessment of the customs value of goods process;
- To ensure proper implementation of the Union Customs Code;
- To enhance the information flow between Customs Service and other relevant authorities aimed at monitoring the quality and safety of goods to be imported and placed on the market;
- To optimize the procedures of clearance of postal consignments, both at export and import;
- To enable the delaying of import charges mechanism;
- To ensure proper transparency of the public consultation process when designing the new architecture of customs terminals;
- To ensure easy and transparent access to customs simplified procedures;
- To ensure the application of good faith and fair dealing principles when working with businesses.

Food safety

Within the past few years, food safety legislation has undergone an upgrade to EU standards by approximating the regulatory system to that of the European Union. Nevertheless, infrastructure to apply the new set of regulations is missing in certain segments.

- To effectively deliver on the action plan aimed at offering access to domestic products of animal origin on the EU market;
- To set up a system for collecting and processing expired food products;
- To implement a risk-based management system when performing inspections at the border inspection points;
- To ensure the timely development of subsidiary regulations aimed at implementing the Law on food safety, etc.
- To eliminate redundant permissive acts that hinder the optimization of the trade process (such as the Sanitary-Veterinary Certificate, conformity certificates, etc.).

Labeling requirements

The new labeling requirements imported from the EU acquis challenge the local producers both in terms of the period necessary to shift to the new requirements, but also in terms of costs and know-how to be applied.

- To ensure timely development of subsidiary regulations aimed at

implementing the Law on informing consumers about food products, therefore to review the opportunity of prolonging the date of application;

- To eliminate the legal discrepancies between the domestic law and the EU Regulation 1169/2011.

Compensatory levy for private copy

The Law on copyright and related rights vaguely explains the application of the private copy levy and fails to provide an explicit list of the items for which the private copy levy applies. On the other side, the quantum of the compensatory levy granted by the law to right holders is minimum 3% of imported goods' value, which is one of the highest compensatory levels in the world.

The law has been excessively and abusively interpreted by the beneficiaries of the collected levy (Collective Management Organizations), that claim for the remuneration in amount of minimum 3 % applied on various items, such as smartphones, computers, and other similar devices, pretending that these devices are used for the production of private copies.

- To consider decreasing significantly the value of remuneration (down from 3%), which will reduce the financial burden on economic operators;
- To reshape the mechanism and procedures for collecting and distributing the remuneration levy.

PRIORITY VI: Enhance the Financial Services Usage

Access to finance

According to the World Bank Domestic credit to private sector (% of GDP) Index is 27.5, being a quite low performance in comparison with the region (Serbia – 54.7). Therefore, more effort is needed to encourage businesses credit themselves and to grow, on one hand, and institutional creditors to lend, on the other hand.

- To encourage institutionalized lenders to finance SMEs by providing relaxed provisioning requirements;
- To encourage the establishment of a single data base of credit histories and insure exchange of data among existing credit history bureaus;
- To simplify the procedure of getting client's consent to access his personal data through digital means of communication;
- To upgrade the functionality of the collateral Registry;
- To streamline the procedure of registering the pledges by providing effective means to banks and non-bank credit organizations to act as registrants;
- To facilitate the financial inclusion of SMEs by providing access to State Lending Guarantee Fund and to "Livada Moldovei" through non-bank credit organizations;
- To allow non-banking credit organisations to participate to the State program "Prima casa" along with banks;

- To develop crowdfunding and P2P lending regulations;
- To streamline the procedure of registering the pledges by providing effective means to banks and non-bank credit organizations to act as registrants;
- To urge the implementation of the Electronic Register of Power of Attorneys;
- To simplify the procedure of certification of independent legal ad-vice for potential guarantors;
- To streamline the enforcement procedures.

Payment services

The National Bank of Moldova implements gradually the 2nd Payment Services Directive, thus assuring a smooth transition to stricter regulations, but also opening new opportunities to non-bank payment services providers.

- To develop and implement the strategy on reducing the cash in the domestic economy
- To promote the development of efficient infrastructure to support the advancement of payment instruments and mechanisms to meet retail payment needs.

Insurance

The insurance sector is underdeveloped and continues to fight against unfair competition. As a series of insurance companies are suspected to experience difficulties in

complying with solvability requirements, there is a permanent risk on the country's membership in the inter-national system of cross border motor liability insurance ("Green Card"). Due to ongoing turbulences on the financial market, the Republic of Moldova has remained under special monitoring for over two decades, thus risking to be banned from the system in case it cannot redress the financial stability of the sector by 2020 as per the decision of the General Assembly of the Council of Europe.

In order to improve the stability of the insurance sector and avoid the risk of suspension from the Green Card system the following measures should be considered urgently:

- To redesign the insurance market according to the principles set in the EU Directive on insurance distribution;
- To ensure transparency in disclosure of the indicators regarding financial stability of the insurance companies. Strict control of stability indicators of the insurance companies in particular concerning the long-term solvability and liquidity ration and the quality of assets covering the insurance reserves in order to avoid any issues in claims payment in advance;
- To assure the implementation of prudential norms and corporate governance principles within the insurance companies;

- To address the financial stability concerns of the Moldovan National Bureau of Car Insurers (BNAA) in order to eliminate the risk of Moldova being suspended from the International Green Card System;
- To assure that auditing of insurance companies is done by professional and well recognized auditing companies;
- To accelerate and finalize the fraud investigation related to embezzlement of assets from BNAA via local banks and measures to ensure the recovery of these assets;
- To ensure proper and unbiased compliance with the price policy regulations for compulsory insurance products (MTPL and Green Card);
- To consider substituting the insurance agreements with insurance policies, thus boosting the digitalization of insurance products and follow the international practice.

PRIORITY VII: Focus on Industrial Policy

CROSSECTORIAL

Free Economic Zones & IT Parks

Free economic zones and IT Parks proved to be successful ecosystems that continuously attracts significant FDI in the country. Therefore, it is of a paramount importance to ensure tax and regulatory predictability to the residents established within these platforms.

- To ensure predictability of the tax and regulatory framework particularly designed for FEZ and IT Parks residents.

Environmental regulations

Although historically environmental legislation has not been considered as a concern for business, in the light of state commitments to implement the EU environmental law, principally new obligations are imposed on the private sector.

- To ensure the implementation of critical provisions from the EU regulations in the Law on waste, including those regarding the incineration and co-incineration of waste, thus supporting the creation of a sustainable waste management system;

- To implement the Extended Producer Responsibility approach by taking into consideration the best EU practices, and by reviewing the Law on payment for environmental pollution;
- To elaborate transparent and clear methodology for wastewater treatment tariffs;
- To ensure proper integration of the new requirements related to environmental legislation in the current regulatory framework.

Industrial Safety Regulations

The recent arbitrary amendments made to the Law on Industrial Safety of Industrial Dangerous Assets significantly increased the insurance premiums (40 - 100 times), thus hindering the competitiveness of the SMEs involved in processing and manufacturing.

- To ensure the revision of the Law on Industrial Safety of Industrial Dangerous Assets by implementing a risk-based methodology to the calculation of insurance premiums.

SECTORIAL

Electricity supply

Moldova has been lately ranked as one of the riskiest countries in the world in terms of short-term energy security.

- To diminish its high dependency on Russia's energy resources, Moldova has pursued some initiatives / projects

in diversifying its routes and supplies, such as:

- Interconnection with the European electricity grid (ENTSO-E) and creation of a transparent and competitive electricity market;
- Promoting the production of energy from renewable sources;

Increasing the share of renewable energy in the generation mix by scaling-up investments through a robust competitive bidding process that can deliver a high volume of capacity at lower costs is one of the main goals of the NAPRE (National Action Plan on Renewable Energy) and the Renewable Energy Law.

The Law on renewable energy is still in its infancy and it will take the Moldovan authorities doing their best to see serious energy players from the EU coming in.

Some of the open tasks left are: approval of a bankable power purchase agreement to be signed with central supplier; publishing an auction calendar by the Ministry of Economy & Infrastructure; approving the cap price and feed-in tariffs by ANRE. The answers to these questions are still to be provided and applied in practice.

Even though the interconnection project has been approved, a time estimation to start and finish the works has not been established. Despite diversification efforts, Moldova's energy security remains fragile in the short term.

Telecommunications

The telecom industry is of an utmost importance to Moldova's economy by supporting the development of the IT industry, contributing significantly to the gross domestic product, that also represents the largest taxpayers and employers in the country. Nevertheless, the industry encounters several problems that may compromise its commitment to further invest in Moldova.

- To abolish or reduce the 2.5% of the sold services sale income tax, paid in the fund for population support;
- To reduce the amount of the portability fee and its exclusion in the case of allocated numbers for broadband mobile services; as well as to grant the right to allocate and return smaller blocks of mobile numbers;
- To consider imposing to the other-the-top service providers similar regulations to the ones for the mobile operators, in terms of registration on the territory of the Republic of Moldova as entities subject to taxation;
- To ensure the effective implementation of the new Law no. 28/2016 on access to properties and shared use of the infrastructure associated with public electronic communications networks, especially as regards the calculation of new fees to be paid by operators for access to properties;
- To implement the protocol decision on the measures for organizing the interaction in the field of telecommunications concluded with the Transnistrian side in a way that takes into account the economic interests of the national mobile phone operators.

Healthcare

There is a persistent need for the development in Moldova of a transparent, efficient and non-discriminatory market for pharmaceuticals, medical equipment and healthcare services in Moldova.

A continuous cooperation among all stakeholders - public and private - should center on a common vision of reform in healthcare aimed at granting access to affordable and qualitative health services for Moldovan citizens, thus rooting in the perception that Moldova is a safe place to leave and work.

The market of pharmaceutical products and medical services is a specific market, that indeed needs closed supervision and regulation from the state authorities.

However, excessive and unjustified regulations of the market, related, among others, to price control regulations, authorization, etc, without a proper background analysis and lack of functional control mechanisms, lead to market distortions, reduction of investments, and scarcity of products.

- To align core national legislation related to pharmaceuticals and medical devices with relevant EU Directives and Regulations, such as:
- Community Code relating to medicinal products for human use, to be transposed into national Law on medicines, to become the key regulatory document governing the health sector;

- Community pharmacovigilance rules for both drugs and devices, to be transposed and enforced via national Regulations;

- Community drugs' quality assurance and safety systems;

- To enact clear and transparent mechanism of drugs' compensation from state budget, as an essential premises for granting access of the population to pharmaceutical products;
- To further improve national healthcare procurement system that will allow the country to continue supplying patients with the necessary qualitative medication in a timely manner;
- To monitor closely the proper implementation of rules on ethical drug promotion to persons qualified to prescribe or dispense drugs and thus enforce ethical & transparent behavior of pharmaceutical market players in accordance with global good practice manner;
- To implement further GxP standards (GMP, GDP, GPP).

Organic agriculture

Moldova's organic sector has considerable potential for growth. Proximity to the EU market offers Moldova farmers a competitive advantage, especially in light of the Deep and Comprehensive Free Trade Area.

- To ensure access of domestic organic products on international markets by simplifying the rules of entrance in Moldova of EU certification bodies;
- To continue subsidizing the organic farming.

PRIORITY VIII: Advance on Digital Transformation

Personal data protection regulations

The Republic of Moldova has begun the process of implementing the new EU Regulation on the protection of personal data (GDPR) into the national legislation.

- To remove the legislative inconsistencies between the EU regulation and the draft national legislation, the transposed regulations being stricter, without the argumentation of the proposed solutions;
- To ensure correlation between data protection regulations and other competing provisions that impose on operators the obligation to collect data that may be personal data (i.e. AML regulations), avoiding any impediments and tensions for operators to fulfill their legal obligations;
- To review the attributions of the National Center for Personal Data Protection;
- To ensure the correlation of the fines with the damage caused and to optimize related control procedures taking into account the economic and legal realities of the Republic of Moldova.

Integration and interoperability of different state platforms

Implementation of the open data policies is crucial not only for the businesses but also the whole society.

- To further ensure the digitalization of public services rendered to businesses;
- To ensure full interoperability between public registries and institutions;
- To provide access of business to state owned registries at reasonable fees;
- To further digitalize the Register of Subjects Required to Declare Wealth and Personal Interests;
- To support the establishment of an interoperability platform between State Tax Service, bailiffs and banks.

Public Acquisitions

Currently, through the MTender system, companies can simultaneously participate in several procurement procedures that take place in different parts of the country, which do not require physical contact with authorities, thus significantly reducing the risks of corruption.

- To ensure the full functioning of the MTender;
- To monitor the way the MTender works, continuously improving it and ensuring a high degree of efficiency, including by permanently adjusting the legal framework to its functionalities.

AMERICAN CHAMBER OF COMMERCE IN MOLDOVA

WWW.AMCHAM.MD

45 B PUSKIN STREET
CHISINAU, MOLDOVA

INFO@AMCHAM.MD