

AmCham MAGAZINE macedonia



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SPOTLIGHT: MACEDONIA'S INSPECTION REFORM

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Dear AmCham Macedonia members and friends -

Thank you for picking up the summer 2016 edition of AmCham Macedonia Magazine. This is our 50th magazine issue, but the first under a new name and appearance. I hope you'll like our new look and continue to benefit from our consistent and unique insights into a wide variety of issues important to internationally-oriented companies working here.

This issue focuses on inspection-related trends and challenges. In addition to an interview with the President of the Inspections Council, we've included information on internationally-funded reform efforts as well as the results of a member survey. We've also included pieces on several current hot topics ranging from U.S. trade policy progress to persistent expat visa and permits issues here in Macedonia.

In internal news this spring, we submitted official comments to the Ministry of Economy on Company Law article 384; gathered interested members for member-to-member learning sessions with Paynet Macedonia and PWC Academy; organized a promotion of Skopsko Smooth on behalf of our members, Pivara Skopje and Ecotip; launched our Companies Giving Back Database; and successfully placed 10 students from low income families in our member companies.

We look forward to continuing our cooperation with everyone this fall and wish all of our readers a reinvigorating summer vacation.

Sincerely,

Michelle Osmanli
Executive Director

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Interview with Irinka Kjoseva, President of the Macedonian Inspections Council



INSPECTIONS COUNCIL LICENSES FIRST INSPECTORS

In October 2013, the Macedonian Government established an autonomous Inspections Council (IC) with the purpose of coordinating the work of inspectorates and promoting the inspections reform in the country. The IC should help ensure the independence of the inspectorates in budgetary affairs, human resources, preparation and approval of annual work programs. This should include establishing methodologies for monitoring the effectiveness of their disciplinary measures in line with best practices.

ACM: How many inspectorates and other bodies carrying out inspections do we have in Macedonia? How many of them are under the direct authority of the Inspections Council?

Kjoseva: In Macedonia there are 14 inspectorates that operate as separate legal entities; there are also a number of inspectorates organized as organizational units within the State administration, the local government units and the municipalities. The Inspection Council coordinates and monitors the work of all inspectorates with the exceptions of inspectorates within the Ministry of Defense, Ministry of Interior, Ministry of Finance, local government units and the City of Skopje.

ACM: By law, what is the IC's main purpose? What has been accomplished so far?

Kjoseva: The IC has a wide scope of responsibilities but is primarily responsible for monitoring and coordinating the work of the inspectors and inspectorates, preparing methodologies and working procedures of

inspection departments, conducting training sessions for professional development and training of inspectors, issuing and revoking inspector licenses and the implementation of an electronic system for inspection services (e-inspectorates).

In the past two and a half years since its creation, the Inspections Council managed to set the foundations of the new inspection system in the country. All bylaws incorporated in the Law of Inspection Oversight were proposed by the Inspections Council. We manage registries for monitoring the work of inspectorates, we formed a group of 60 educators from among the inspectors who conduct training for 45 different types of inspectors and we successfully conducted the first inspector exams, followed by issuing the licenses to those that passed.

ACM: How often do individuals and legal entities object to the work of inspectors and are these complaints substantiated? What are the main complaints of the inspected entity's towards inspectors?

Kjoseva: The Inspection Council holds regular monthly sessions where we discuss all petitions and complaints filed by individuals and legal entities that are affected by the work of inspectors. In the past year, we reviewed 52 complaints, but in most of them, citizens complained about issues that are under the purview of the State Commission for Appeals in the field of inspection and misdemeanor proceedings; only a few of the complaints were about inspectors' work. On the IC's initiative and in line with the Law on Administrative Officers, we pursued disciplinary proceedings, wherever there was a reasonable suspicion of an inspector offense and also took disciplinary measures. So far, we have not revoked any inspector's license.

ACM: In your opinion, are Macedonia's inspectorates properly equipped and staffed?

Kjoseva: The IC monitors and analyzes staff and technical

equipment of inspectorates and inspection services. Our analysis of staffing shows that 72% of the inspector positions have been filled so far. Realistically, we expect an increase in this percentage in the coming year, with about two hundred civil servants currently working in other jobs within the administration who have passed the inspector exam and are waiting to be reallocated to inspector posts.

Most inspectorates and inspection services face problems due to inadequate technical equipment, such as a lack of vehicles and IT equipment. Though budget funds for this purpose are minimal, some inspectorates – such as the State Environmental Inspectorate – have overcome this obstacle by utilizing international grant funds. We expect this positive practice to be transferred to other inspectorates in the future.

ACM: Tell us about the USAID support you received in creating the „Manual of Inspection Methodology“.

Kjoseva: USAID Macedonia recognized the importance of the reform of the inspection system conducted by IC in Macedonia and supported our work through the „Program to improve organizational operations“ as well as the „Project to promote investment and exports“ within which the „Methodology for conducting inspections“ was developed. The methodology is a handbook for inspectors detailing basic principles upon which modern inspection systems are based. The positive experiences and practices of these systems will be a model and framework for development of the system for inspection in Macedonia.

ACM: Which inspectorates receive the most complaints?

Kjoseva: Inspectorates or inspection agencies range from those with only two working inspectors and those with over 100 inspectors. Therefore, naturally, most complaints received in 2015 are in response to the larger inspectorates such as the State Labor

Inspectorate (16 complaints), the State Education Inspectorate (11 complaints), the State Market Inspectorate (10 complaints) and the State Inspectorate for Agriculture (5 complaints).

ACM: What is more important, increasing the number or the quality of inspections?

Kjoseva: The quality of inspections is more important. Modern inspection systems recognize that it is not practical to search and punish every irregularity, because it requires a large number of inspectors and a large budget to support their work. Frequent inspections create a restrictive environment that stifles innovation and entrepreneurship. The planning of inspections should be carried out based on risk analysis, which is made by processing the available data collected in previous inspections.

ACM: Tell us about your personal career. What will be your personal mark on the work of the Council?

Kjoseva: I am a civil engineer and I have worked both in the private and the public sector. I have been a part of the IC since its creation, first as a member of the Construction, Urban planning and Transport department. I have been the IC President for the past 11 months.

I am proud that in this period we have managed to implement the first licensing of inspectors, which is an important part of the reform of the inspection system in the country. On May 19th this year, the IC granted 1,020 inspector licenses to candidates who successfully passed the inspector exam.

In the upcoming period, the IC will work on the development and implementation of software solutions for inspection services to improve the efficiency and effectiveness of inspections. Also, our activities will be directed toward raising awareness among those being supervised of regulatory requirements, as well as promoting the principle of „voluntary compliance“ with the law.

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AMCHAM MEMBERS ON INSPECTIONS

On June 8th 2016, a survey was sent to all AmCham Macedonia members to discover their current views on inspections. One fourth (28 companies) of our members responded to the survey, majority of them large companies, present in the FMCG, Retail, Law, Tax Advisory and Energy sectors.

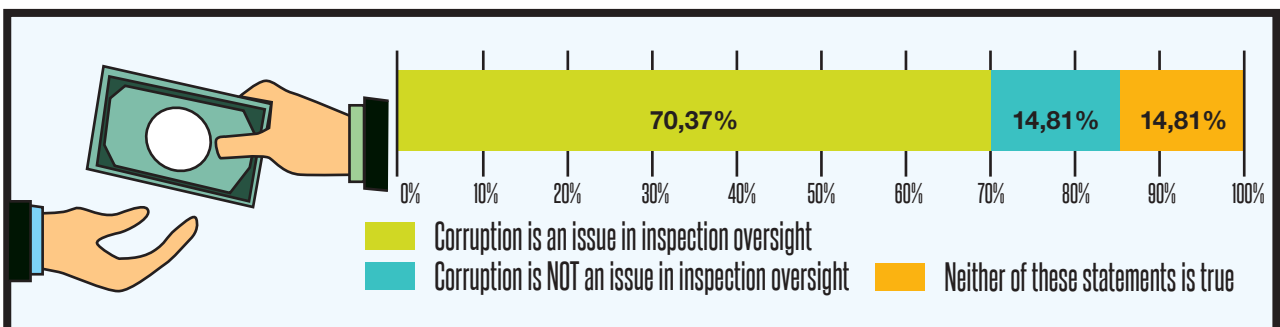
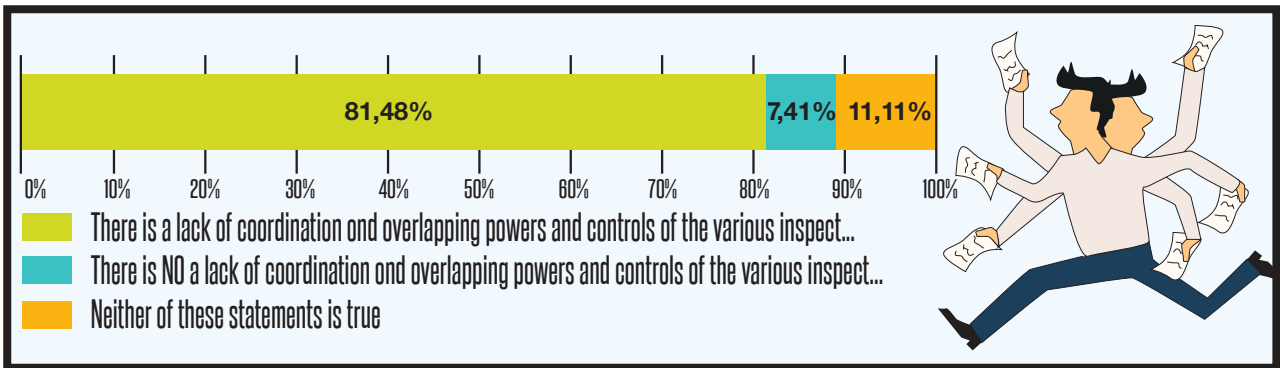
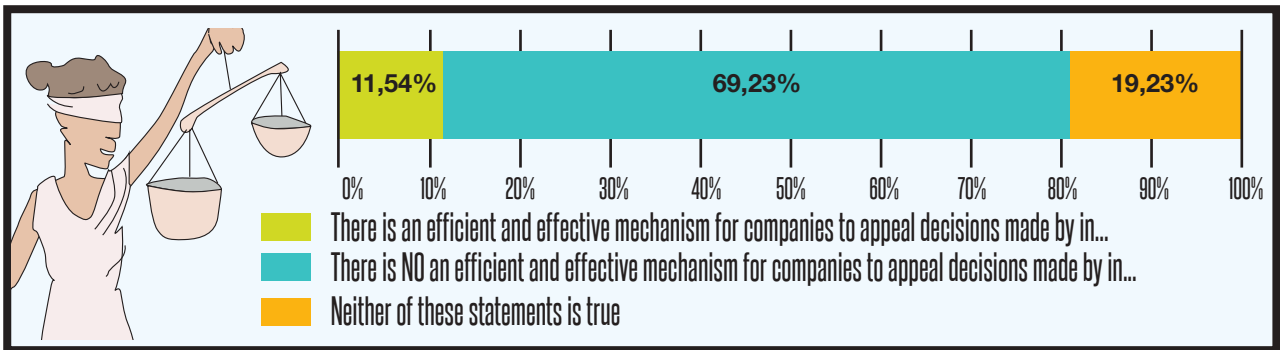
The survey responses suggest that AmCham members are generally satisfied with the number of inspections they undergo each year, as well as with the time their employees spend on each inspection. However 1/3 said inspections negatively impact their operations and about 44% stated that the

regulations governing inspection oversight are inadequate. Inspection areas highlighted as needing improvement included: coordination between inspection bodies; mechanisms to appeal inspector decisions; inspectors motivation to safeguard compliance over issuing files; and corruption. More specifically,

- Respondents said they underwent 5-10 inspections on annual basis. About 80% said that number is appropriate.
- Around 60% answered that the number of hours their employees spend on

- inspections is appropriate. 81% of respondents said "there is a lack of coordination and overlapping powers and controls of the various inspection bodies"
- 70% of respondents said "corruption is an issue in inspection oversight"
- 69% of respondents said "there is NO efficient and effective mechanism for companies to appeal decisions made by inspectors"
- 70% of respondents believe that "inspectors are incentivized to issue fines, rather than ensure compliance and provide guidance to companies."

CHOOSE WHICH OF THE FOLLOWING STATEMENTS DESCRIBE THE MACEDONIAN SYSTEM OF INSPECTION OVERSIGHT:



SERBIA'S INSPECTION OVERSIGHT LAW: A BUSINESS ENVIRONMENT BOOST

This new law is a critical element of Serbia's efforts to improve its business environment and the efficiency of its inspection bodies.



Author: Milan Stefanovic,
USAID Serbia Business
Enabling Project Expert

Until 2015, legitimate businesses in Serbia were subjected to frequent and often unwarranted inspections controls and related misdemeanor fines. This was a significant regulatory, administrative and financial burden for legitimate businesses, while firms operating in the informal economy were often obstructed. This situation is now improving, thanks to an umbrella Law on Inspections Oversight that is being applied by all 34 inspectorates in the country.

After the failure of several inspections reform initiatives in the 2000s, USAID's Business Enabling Project (BEP) began a new initiative in 2011 based on analysis and dialogue, supported by an extensive outreach campaign. Public-private dialogue led to a consensus among businesses, experts, and even many inspectors that Serbia needed an umbrella inspections law that would resolve key issues. The stakeholders agreed that the law should mandate inspections coordination and prevention measures and

practices, and eliminate sanctions for unintentional offenses. An umbrella law would ensure consistency of procedures and methods and effective and efficient protection of citizens and legitimate businesses.

Despite this consensus and the fact that 78% of businesses in the USAID BEP's 2011 Business Survey stated that inspections were one of the major constraints to their competitiveness, the Government of Serbia showed weak interest in inspections reform. In response, the project continued working with business associations to publicize problems and advocate for inspections reform. Also, the project's experts worked with inspectorates on a Model Law on Inspections and developed studies on how inspection oversight could be improved as well as the key role of inspections in fighting the shadow economy.

Finally, the USAID BEP together with AmCham Serbia and other business associations finally succeeded in obtaining a commitment from the Ministry of State Administration and Local Self-Government to reform the inspection oversight system. The Ministry and USAID BEP jointly developed the Explanatory Concept of the Draft Law and Draft Law on Inspection Oversight, based on the Model Law on Inspections. Project and Ministry experts also developed a comprehensive Rationale and Regulatory Impact Analysis. In parallel, the Government of Serbia adopted a Strategy on Public Administration Reform, which included inspections reform as a strategic priority (that section was jointly developed by the Ministry and the USAID BEP).

From the outset, the drafting process was extremely challenging, particularly because of frequent changes in Government and severe resistance within most inspectorates to the changes. All these challenges were overcome thanks to comprehensive and persistent technical support by Serbian and foreign experts, a well-structured strategic communications campaign, and substantial public-private dialogue. A new Law on Inspection Oversight was adopted on April



15, 2015. Transparency Serbia described the inclusive legislative development process as a best regulatory practice and an example of how all laws and regulations should be developed. The Law also received positive reviews from the EU Commission and business associations.

This new law is a critical element of Serbia's efforts to improve its business environment, which had been plagued by inspection bodies that were uncoordinated and focused on punishment rather than compliance. Thanks to USAID BEP's work with the Ministry and a wide group of stakeholders, the new Law is transforming the way inspections are conducted. The Law on Inspection Oversight incorporates modern inspections standards and features, including coordination of inspections, risk assessment, advisory role, preventive measures, and provisions related to decreasing the grey economy and ensuring fair competition. The Law also enables more efficient and cost-effective inspections, stronger and standardized inspection oversight, and increase in knowledge and skills of inspectors. The Law requires all inspectorates to react to illegal businesses or behavior. This is a huge step forward in fighting the grey economy, and is already changing inspectors'

previous practice of heavily supervising and burdening legitimate businesses, while declaring incompetence to respond to illegal business entities or actions.

To facilitate proper implementation of the reform, the USAID BEP helped develop bylaws for the Law. USAID BEP also developed a comprehensive Guide for Application of Law on Inspection Oversight, with explanations, recommendations and models of enactments, as well as four methodologies.

The new Law became fully effective on April 30, 2016, with provisions relating to inspection of unregistered businesses having been effective since August 2015. As expected, the new legislation pushed businesses in the "shadow economy" to legalize. Data released by the Serbian Business Registers Agency show a significant increase in registration by previously grey businesses during the first month of the Law's full application. In May 2016, there were 58% more newly registered businesses than in May 2015. Previously, when the Law mandated inspection oversight of unregistered entities in August 2015, the Agency registered 71% more entrepreneurs than in August 2014. Businesses are also starting up and expanding as a result of inspections getting fairer, more transparent, and less burdensome.



The USAID BEP continues to work with the Ministry, inspections, and business associations to improve inspections and have a greater impact. Pursuant to an implementation plan adopted by the Government of Serbia, the USAID BEP and its partners are developing and adopting by-laws, establishing the coordination mechanism (managed by the Coordination Commission), launching and maintaining the e-Inspections system, developing training and manuals for inspectors and businesses, monitoring inspectorate implementation, and communicating with the public. The project also implemented a Train the Trainers Program that has trained 327 inspectors to train their colleagues across 34 inspectorates. The trainers have in turn trained 3,184 inspectors.



Everyone has their own story. One team. **One goal.**



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EU SUPPORTS ENVIRONMENTAL INSPECTION IMPROVEMENT EFFORTS

Since January 2015, an EU-funded project has been working with the Macedonian State Environmental Inspectorate (SEI), as well as with authorised environmental inspectors from municipalities, to improve their effectiveness and align with EU best practices¹. The request to the EU for support by the SEI through the Ministry of Environment and Physical Planning (MoEPP) began in 2011 in response to the persistent gap between new EU environmental requirements transposed into national legislation, and the actual level of implementation by industry and other relevant stakeholders. This gap had been – and remains – cause for concern both for the Macedonian environmental authorities as well as for the European Commission, which emphasized in the country's last annual progress reports the need to close such gap between theory and practice.

To meet the need, 3 EU co-financed actions were designed to: support environmental inspection at central and local levels; provide technical assistance to 9 pilot municipalities and MoEPP in other duties related to implementation of environmental legislation at the local level; and provide various kinds of equipment and software to improve the working conditions of environmental inspectors in the country, including a set of vehicles, measuring equipment, office IT equipment, and a document and process management software. Implementation took place from 2015-16.

The "Twinning" project mainly benefitted SEI and the EU counterparts were the Spanish Galician Regional Ministry of Environment and Spatial Planning and The International and Ibero-American Foundation for Administration and Public Policies (FIAPP) and the Netherlands' Ministry of Infrastructure and Environment. This project mainly aimed to:

1. improve the laws that define the environmental inspection system and how environmental inspectors work;
2. suggest changes to optimize the resources of the institutions involved in environmental inspections;
3. improve the planning of environmental inspection authorities, prioritizing the solution of the biggest environmental problems detected;
4. deliver or support the elaboration or improvement of numerous tools for the daily work of inspectors and industrial operators; and
5. raise inspector capacity with training utilizing the tools created by the project.

The final goals were to help create an SEI: (I) that is results-oriented (environmental compliance of industry), with fewer inspections but in more depth; (II) whose efforts are based on risk analysis; (III) whose work is more standardized throughout the country, and in line with EU best practices.

¹For more detailed information and access to project outputs please visit www.sei.gov.mk.

²IMPEL: EU Network for the Implementation and Enforcement of Environmental Law

Authors:



César Seoáñez



Darko Blinkov

Project Coordinators, "Strengthening the administrative capacities at central and local level for implementation and enforcement of the environmental acquis", an EU Twinning Project running from January 2015 - August 2016

THANKS TO THE ACTIVE INVOLVEMENT OF ALL PARTNERS, THE PROJECT PRODUCED THE FOLLOWING KEY RESULTS:

Improvement of the environmental inspection and enforcement system, including:

- Draft of Law for Inspection on Environment, aligned with certain provisions of EU legislation;
- Macedonian version of the EU IMPEL² risk assessment IRAM software, for inspection planning;
- Strategy Report with proposals for the further improvement of the environmental inspection system;
- Proposals on how to establish a good system of performance indicators for the SEI and its inspectors; and
- Proposals to improve and upgrade current SEI software.

Training and capacity building, including:

- Strategy Report defining training curricula & long-term capacity building proposals for SEI;
- Delivery of 12 training missions covering the environmental inspection cycle, knowledge of industrial sectors & abatement pollution techniques, inspections to pilot installations, sampling & monitoring, capacity building on communication and team building and use of IRAM software; and
- Implementation of 3 study tours with Macedonian inspectors, to Spain, Portugal and the Netherlands.

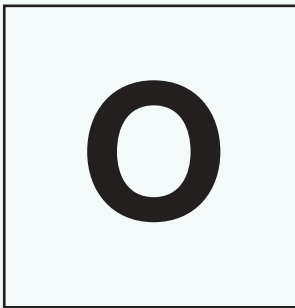
Inspector support, including producing the following:

- An Environmental Inspection Manual;
- A Generic environmental inspection check list;
- A Horizontal Best Available Techniques inspection check list;
- 12 sectoral environmental inspection check lists;
- 12 sectoral factsheets (to know the sector & techniques to minimize its pollution);
- An inspection report template for inspections to installations subject to Directive 2010/75/EU (largest polluters); and
- Guidance in cases of small incidents or accidents.

Stakeholder communication, including:

- SEI website, including information for companies, Frequently Asked Questions, legislation, all relevant documents; and
- An informative leaflet for industrial operators.

OVEREXPOSED: EXCESSIVE BOARD MEMBER DISCLOSURE RULES



In May 28th, 2015, Macedonian Parliament adopted a number of amendments to the Company Law. An amendment made to Article 384 requires that the annual reports of public companies in Macedonia include details of the global employment- and/or Board service-related earnings (salary, other remuneration, bonuses, insurance and other rights) of each member of their executive & non-executive boards, management boards and supervisory boards.

While government efforts to further enhance the protection of minority investors are commendable, the amendments made to Article 384 far exceed what is necessary and reasonable to achieve this goal. In fact, this new requirement could negatively impact internationalized companies working in the country as it seems to lack legal legitimacy and differs from global best practices. AmCham communicated its position based on feedback from over 15 organizations to the Ministry of Economy (MoE) and others in May, including the following arguments:

- **Compensation details are generally not public information.** Many companies consider management compensation and benefits packages as a trade secret, meaning their disclosure in another company's annual report (as required by article 384) could result in negative repercussions for both the individual and the company/group.
- **The EU Shareholder Rights Directive does not require the disclosure** of global compensation details, nor are we aware of another country in Europe that does.
- The obligation to release the earnings from other companies **may discourage foreign experts from serving on the managing bodies of companies in Macedonia**, thus reducing the country's appeal as an FDI destination.
- Information provided by foreign, non-Executive Board members on any earnings outside the company **cannot be verified by company authorities or shareholders.** Yet, article 384 requires Executive Board members and shareholders to sign and accept the validity of these data, as with all contents of the annual report.
- There is **no evidence that measure increased the amount of useful information available** to minority investors. The proponents of the amendments stated that "the changes were made in line with Doing Business 2015 report", however that report doesn't recommend such provisions. Moreover, the Doing Business 2016 report, doesn't mention this change as a positive development in the Company Law.¹

On June 21st 2016, AmCham received MoE's response and a few weeks later, the Constitutional Court decided not to review Article 384 (in response to an initiative independent of AmCham)². The MoE response to AmCham's position and the Constitutional Court ruling were virtually identical. The key arguments were that:

- Board members' privacy is not violated by the measure because companies should not disclose sensitive Board member details to uninvolved third parties;
- Individuals that do not want to divulge their global compensation details can simply NOT serve on the Board;
- 18 other countries require disclosure of information on whether Board members are members of management structures in other companies, as well as information on their primary employment.

Unfortunately, the first argument directly contradicts Company Law article 388-b, which states that public-listed companies must publish online all documents and materials that will be reviewed at meetings of their shareholder assemblies. In other words, it is impossible to limit the distribution of the annual report to shareholders. The second argument seems to welcome a narrowing of those willing and able to serve on Macedonian boards, dismissing any potentially negative impacts of such a trend. Finally, the 18 countries cited by both institutions do not require Board members to disclose their global salary/compensation details.

Neither the MoE nor the Constitutional Court demonstrated how disclosing Board members' global compensation details to the general public is a legitimate, appropriate and necessary part of protecting shareholders from damaging interested party transactions. In our view, requiring Board members to disclose the existence of an employment, Board service and/or consulting relationship with other organizations is sufficient.

¹ Doing Business 2016 report - <http://www.doingbusiness.org/reforms/overview/economy/macedonia-fyr>

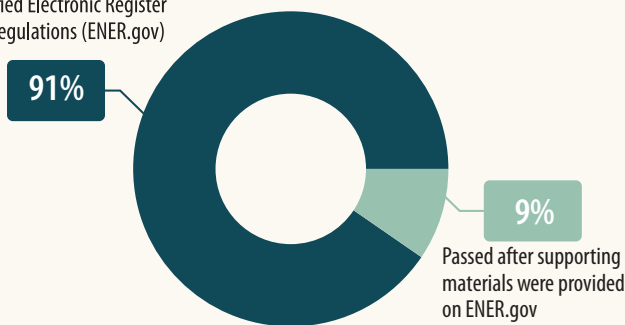
² Constitutional Court Decision - <http://www.ustavensud.mk/domino/WEBSUD.nsf>

PUBLIC CONSULTATION PRACTICES

Macedonian Government January 1 - June 30, 2016

A total of 199 laws & amendments were passed during this period.

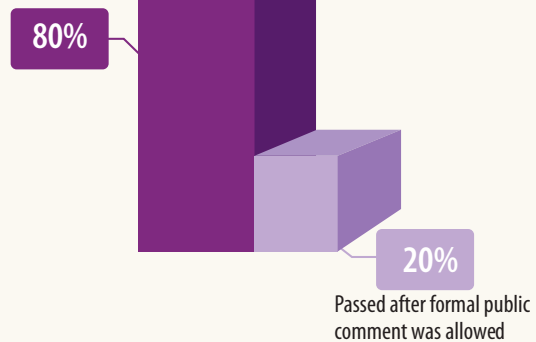
Passed without any supporting materials being published in advance on the Unified Electronic Register of Regulations (ENER.gov)



Citizens were not provided details on proposed laws & amendments prior to their adoption by Parliament 91% of the time.

Public comments were never officially invited for 80% of laws and amendments adopted during the first 6 months of this year.

Passed without allowing formal public comment



6 amendments were made
to
5 key economic laws



4 of these changes were made without any formal public comment period.

Nothing was published on ENER.gov for any of these changes.

Sources: www.sobranie.mk @ www.ener.gov.mk

Analysis: AmCham Macedonia

Domestic Drug Market is Becoming Less Attractive



WHY IS BIG PHARMA LEAVING MACEDONIA?

The regulation of drug prices, or their repeated reduction, as well as parallel imports of medicines have led to a decline in the interest of large global pharmaceutical companies in the Macedonian market.

Author: Igor Petrovski
for Kapital magazine
issue 855 – Special
Pharmacy Feature,
date:18.03.2016

Only two new drugs or “molecules”, as they are called in the industry have entered the “positive list” of the Macedonian State Health Insurance Fund in the last eight years, according to our sources who are insiders in the drug market but insisted on remaining off the record on the topic. The absence of new, innovative medicines on the list of drugs for which the State fully or partially covers costs, causes a few adverse effects, they say: citizens have limited ability to treat themselves with modern medicines and the world’s major pharmaceutical companies that are manufacturers of these drugs are slowly losing interest in the Macedonian market and closing their offices or reducing their operations, leaving them with 2-3 employees here.

Almost all of the world’s major pharmaceutical manufacturers that have launched new molecules or formulas

of innovative drugs into the global market over the past 20 years established a presence in Macedonia. In practice, they are not direct distributors of their own program; the distribution is done by wholesalers, their local partners. Local representative offices of big pharma companies mainly deal with after-sales activities, analysis of the use of their drugs, marketing activities and the like.

In recent years, we've witnessed a trend of big pharma companies closing their offices. Our sources say that the pharmaceutical giants Astra Zeneca, Actavis and Stada already closed their offices and several companies downsized their staff, reducing and refining their basic operations down to basic registration of medicines, etc. The closure of their local offices does not mean that their products will not be present on the market, though, drugs for which manufacturers have no income from the Macedonian market may be withdrawn. These are more expensive drugs that are not on the State Fund's positive list and are not viable for commercial use, given the small market.

"We all lose from the withdrawal of global pharmaceutical companies from the country. Health workers can't treat patients with new drugs

to their benefit. Patients can't participate in sponsored studies, so they can benefit from the latest pharmaceutical achievements. As prices of generic drugs start to fall (drugs produced after patent protection of the original formula expires, usually ten years after their original placement. The manufacturing cost of these drugs is much lower because costs of research and development are not embedded), profits will decrease and we will lose the margin that usually supports the import of innovative medicines," according to our sources.

What kind of drugs are Macedonian citizens treated with?

Generic drugs are of good quality, but how to get more innovative drugs on the positive list?

Do cheaper, generic, outdated medicines, with formulas synthesized 20-30 years ago, dominate the market?

Pharmacists with whom we spoke said that drugs in Macedonia

have the required quality and are safe, at least those that enter legally (i.e., following the required procedures of registration, distribution, storage, etc.). The Medicines Agency has stated repeatedly that citizens can sleep peacefully: drugs entering the market under their control are safe in every way. The generic drugs policy used by the government does not mean that drugs lack quality, pharmacists explain. These are drugs that are made by a formula that was invented by major pharmaceutical companies/ market innovators that initially had exclusive rights to market the formula, before other companies obtained the right to produce these drugs under license. These new drug innovations are expensive because several billion dollars are usually spent in research and development of the new drug molecule.

After the patent protection period expires, all generic companies in the world can produce their own drug and under their own brand, based on the new formula. Treatment with innovative drugs is expensive, therefore, global practices regulate the drug market, aiding public procurement policies and subsidizing innovative drugs, so they are available to the population.

Continued on page 24



PARALLEL IMPORTS JUST "POUR OIL ON THE FIRE"

Four years ago, the State began allowing parallel imports of medicines, meaning the ability to import a drug that is already registered in Macedonia, but is found cheaper in the list of countries that allow parallel imports. Minister of Health, Nikola Todorov, defended this measure stating that it will allow increased market competition and cheaper drugs for patients. Representatives of wholesalers say that the interest in this list increased as soon as Russia and Turkey were added to it - because of the size of these markets and the possibility of finding lower-priced drugs - domestic wholesalers began to import more drugs with this type of import.

We received a similar perspective from several pharmaceutical workers, managers and wholesalers offices of global pharmaceutical companies about the consequences of parallel imports:

a) They impede the traceability of drugs, from the manufactur-

er to the end user in Macedonia;

b) They increase the likelihood of counterfeit medicines entering the market, particularly from markets outside the EU, Russia and Turkey;

c) They circumvent the major pharmaceutical companies worldwide, further reducing the attractiveness of the Macedonian market for them.

Our sources state that there are sufficient regulations to reduce prices and that parallel imports aren't necessary, since many drug prices are already reduced to levels that are unattractive to manufacturers and wholesalers. It is worthwhile to note that for the purpose of this text, we sent questions to the Medicines Agency for their position on parallel imports and their effects, as well as to comment on not having new innovative drugs added on the positive list, but did not receive an answer.

MONEY WELL SPENT? PUBLIC PROCUREMENT IN THE WESTERN BALKANS

Poor planning, selection of the bids based solely on the lowest price criterion and insufficient institutional capacity to implement tenders and control are common problems in public tenders in four Western Balkan countries, including Macedonia. Research on the effectiveness in public procurement in Macedonia, Serbia, Bosnia and Herzegovina and Montenegro done by a regional civil society organization (CSO) network, Balkan Tender Watch, shows a constant decrease in the average number of bidders per tender in all four countries in the last four years. This, according to the researchers, indicates an increased level of corruption and mistrust in public tenders. Beside comparative analysis of legal and institutional frameworks, the research included direct monitoring of selected procurement cases of the same types of products and services. Findings suggest questionable public procurement purposefulness (i.e., necessity of a given purchase and value for money) in all four countries. In their recommendations, CSOs ask for the EU integration process to be used to push beyond the minimum *acquis* requirements, given that research indicates wide room for corruption and mismanagement of public spending while EU legal requirements are largely met.

In Macedonia specifically, the lowest price as single bidding criterion, mandatory e-auctions and the obligation



Author: German Filkov,
President at the
Center for Civil
Communications

BALKAN TENDER WATCH

Center for Civil Communications
Центар за граѓански комуникации

for contracting authorities to obtain prior approval from the Public Procurement Council constantly decrease competition, compromise quality of purchases, cause a high number tenders to be annulled and jeopardize the 'best value for money' principle. Once very close to being fully harmonized with the EU requirements, the countries' public procurement regime is now further from being aligned with the *acquis*. The following list summarized issues identified at each phase of the procurement process:

- Public procurement planning is one of the country's weakest phases; annual procurement plans are considered *pro forma* by contracting authorities. The research showed a lack of analyses required to ensure the best value for money in public spending.
- The contracting phase is complicated, lasts longer and is more expensive due to the obligation for contracting authorities to seek approval for tender specifications prior to them being published. While this step was added to increase competition, the number of bidders per tender keeps declining, causing

a series of distortions in the market.

- The contract management phase is the most secretive one. Given that the Public Procurement Law ends with signing the contract, there is no publicly available information on the execution of the contracts. Simultaneously, the scope of documents contracting authorities submitted during the research through the Free Access to Information Act for this phase was very limited and incomparable to the documents for the other phases of the monitored tenders.

Research findings and various forms of best practices in CSOs monitoring of public spending were presented on an international conference: Public Procurement Oversight: Corruption Risks Identified by the CSOs, which took place in Skopje on June 7, 2016, organized by the Center for Civil Communications and the Macedonian Center for International Cooperation. Various stakeholders, including contracting authorities and business people agreed with the findings, adding more insights to the problems and emphasizing the urgent need for legal changes to bring the procurement system back on track with EU requirements.

FOREIGN INVESTORS SATISFIED WITH EMPLOYEES, SUPPLIERS & TAX POLICY IN MACEDONIA

By: Vlatko Stojanovski, Foreign Investors Council Coordinator, Economic Chamber of Macedonia

Foreign investors are satisfied with doing business in Macedonia and 84% of those surveyed would invest again here, if given the opportunity. This is the conclusion of the latest survey conducted by the Foreign Investors Council, on which 52% of its members responded in the period from March to April 2016. Survey results were presented by the Council President, Stefan Peter, at a press conference held on May 23, 2016. "Proof that these are not empty words is the decision of Van Hool to open a second production line, as well as the announcement of Johnson Controls to build another factory in Strumica," said Peter.

According to the managers, key factors for doing business in Macedonia are: a qualified workforce, the level of business expenses, tax policy, legal stability, a stable business environment, the geostrategic location of Macedonia and its proximity to the EU, as well as its political and macro-economic stability.

According to the survey, 68% of companies managed to meet planned business activities, 72% do not expect any changes in the implementation of their business plans, and 20% expect improvement. Only 8% predicted their economic performance to worsen in the coming period, but they, as Peter said, are mainly export-oriented and their business depends on contracts for foreign markets. Peter underlined that foreign investors are satisfied with the tax policy in Macedonia, high-quality workforce and stable business

environment, but they continue to face, as reported in the survey, a lack of legal, social and political stability. Problems include administrative procedures, frequent changes in legislation and an insufficient fight against corruption. For this reason, 84% of foreign investors believe that Macedonia's membership in the EU would significantly improve its business environment.

Foreign investors assessed that the protracted political crisis in the country will have long term consequences on the Macedonian economy. "It is possible for foreign companies to postpone investment plans, which is expected. But if the political environment stabilizes quickly, it will not only attract new investments, but will also help the current investments to expand their business activities," noted Peter.

The Foreign Investors Council has 118 members and marked a decade of existence this year.

WORK & RESIDENCY PERMIT PROCESS REFORM ON PAPER ONLY?

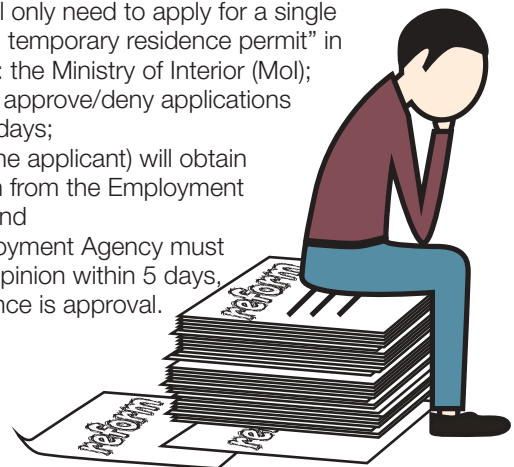
AmCham has closely monitored the expat visa, work and residence permit process for several years now, since it directly impacts a number of our members and is an important part of the country's efforts to attract FDIs. A new Law on Work and Employment of Foreigners (LWEF) was adopted and published in November 2015 and technically came into force on June 19th, 2016. The amended law introduces a single permit process, merging the separate work and residence permits processes of today. Disappointingly, though the law is technically now in force, the process has yet to undergo any noticeable improvements since institutional rule-books, procedures and forms have yet to be issued.

International companies are extremely interested in the full implementation of the new law because the current expat visa and work permit process is unnecessarily bureaucratic and inflexible. As detailed in the summer 2015 issue of this magazine, this is largely due to a lack of public investment in modern IT infrastructure to support modern and efficient processing of payments and applications; a lack

of process transparency and predictability; and an equally defensive approach to all types of visa and work permit applications out of step with the country's FDI attraction goals.

The general hope among internationally-oriented businesses is that – once fully implemented – the new process is going to significantly reduce and simplify the process of obtaining permission to live and work here. Specifically,

- Expats will only need to apply for a single "work and temporary residence permit" in one place: the Ministry of Interior (MOI);
- MOI must approve/deny applications within 15 days;
- MOI (not the applicant) will obtain an opinion from the Employment Agency; and
- The Employment Agency must issue an opinion within 5 days, if not, silence is approval.



Interview With Chris James, CEO of Lynx Resources Ltd, Which Acquired the SASA Mine in Makedonska Kamenica in November 2015

NEW OWNERS OF SASA MINE PLEASED TO JOIN MACEDONIAN BUSINESS COMMUNITY

ACM: Lynx Resources was established by its shareholders Fusion Capital AG and Orion Mine Finance Group to acquire the SASA mine. What led to this decision?

James: Both Fusion Capital and Orion Mine Finance are strong believers in the fundamentals for zinc and lead, and the quality of the SASA mine – which is one of the most competitive lead/zinc/silver mines globally, with a track record of stable production (around 30,000 tons of lead, 22,000 tons of zinc and 400,000 ounces of silver in concentrates each year), and a long resource life of approximately 20 years. We conducted extensive due diligence on the operation before establishing Lynx Resources to acquire the mine, culminating in one of the largest private acquisitions in Macedonia, and in the zinc/lead industry recently.



Our company, Fusion Capital, is a management team focused on the acquisition and management of mining operations, and my partners and I are now the full time management team and co-owners of Lynx Resources. Our largest investor is Orion Mine Finance, one of the world's leading mining-focused investment businesses, headquartered in the United States, with approximately \$1.8 billion under management.

We actually named our new company after the Balkan Lynx, an endangered animal in the region and one of the national symbols of Macedonia as depicted on the 5 Denar coin, to underscore our



Chris James

respect for the region and its natural heritage.

ACM: SASA mine has a long mining history. How useful is the existing infrastructure? What improvements are planned/needed?

James: The previous owners invested in new plant and equipment when they acquired the assets out of bankruptcy in 2005, and ramped up the mine to its production levels of today (approximately 770,000 tons per annum of ore). Our ongoing investments



are primarily to sustain the asset via replacing plant and equipment in accordance with best available technologies, continuing to explore and develop the resource base, and to continue to improve our operating performance, safety, environmental performance and sustainability.

ACM: What factors are driving the commodities market at the moment?

James: Zinc and lead prices have been among the first commodities to start to recover despite the recent global slowdown in demand, which has been largely driven by a weaker Chinese economy and slower growth in Europe and the United States. Like all commodities, price is driven by supply and demand, and the fundamentals for zinc and lead are particularly attractive, with increasing demand driven by an impending tightness of concentrates due to a large number of mines closing globally in the last couple of years (e.g., Century mine in Australia, the world's 3rd largest zinc mine, and Lisheen, another large zinc/lead mine in Ireland). The supply forecast is also positive as demand for zinc continues to grow as standards improve in China and other developing countries to galvanize and protect steel, and demand for lead remains strong for its use in automotive and industrial batteries.

ACM: As a major employer in the area, how would you describe operating in Makedonska Kamenica? What are some examples of how your organization engages with the local community?

James: The SASA mine is the largest employer in the town of Makedonska Kamenica, directly employing approximately 700 people from the region (approximately 90% from the local municipality), and more indirectly in the provision of goods and services to the mine. The mine has a long operating history, as marked by its recent celebrations on June 10, 2016, SASA mine's 10th anniversary since the restart of operations in 2006, and



50th anniversary since the original opening, so there has been a long history of the company and community working together for a positive future.

The revenues from the SASA concession have enabled the construction of local roads, playgrounds, new town square, new fire department, local water supply, energy supply lines, a modern market, sport center, and a center for special needs. In independent initiatives, SASA has also reconstructed local school buildings, provided support for local kindergartens and sporting clubs, built the Miners' Park in the city and 2 playgrounds for children, and frequently contributes to social, educational and charitable programs in the city of Makedonska Kamenica and surrounding regions.

ACM: Please tell us something about your personal career and background.

James: Before establishing Lynx Resources to acquire SASA, myself and the CFO and COO from the Lynx Resources management team worked at Nyrstar AG in Switzerland, one of the world's largest zinc and lead mining and smelting companies. Prior to Nyrstar roles in Zurich and London, I worked at Zinifex and Pasminco, both large global zinc/lead mining and smelting companies with headquarters in my home town, Melbourne, Australia. I have been working in the zinc and lead industry for approximately 15 years, with roles spanning operations, business

improvement, strategy, investor relations, commercial, and most recently corporate development and acquisitions, which provides a unique insight into the industry.

When my partners and I first investigated the SASA mine as an acquisition it was evident that this was going to be a very interesting opportunity due to the attractive scale of the operations, location, cost competitiveness, and quality of SASA's concentrates in the global market.

ACM: You've been present in Macedonia for over a year. How would you rate the Macedonian business climate?

James: We have been very pleased with the strong support we have received from all areas of the business community since completing our acquisition: including government, institutions, other companies, and organizations such as the American Chamber of Commerce. We have found Macedonia to be an excellent place for business, with a well-educated workforce, competitive costs globally, a convenient location for services and sales into Europe and offshore, and a very open and welcoming attitude to newcomers.

Whilst our strategy for Lynx Resources is to continue to grow the company through acquisitions, exploration and development in mining and metals globally, we hope to have a long and fruitful future in Macedonia, and to contribute to its future growth and prosperity.

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Interview with Marian Capkovic, Tetovo Plant Manager, Lear Corporation Macedonia

LEAR CORPORATION AT WORK IN MACEDONIA

Capkovic joined Lear Corporation in November 2015 to manage the new site in Macedonia. He is an experienced automotive industry professional who has worked for automotive original equipment manufacturer in the Czech Republic, Slovakia and Serbia

ACM: Tell us a bit about your local team.

Capkovic: Lear's leading role as a global innovator in automotive seating and electrical distribution systems encompasses more than products and processes - we know that people drive our success and have proven to be our most important asset at every Lear location. We value diversity and inclusion because it makes us a better company and better individuals coming together form an even stronger team.

In Macedonia, we have managed to recruit and hire experienced professionals who reflect and promote teamwork and a "can do" spirit. Also, we focus on as potential hires, those with no relevant experience or local college graduates with potential. One of our core values is being an Employer of Choice; consistent with this, we seek to recruit, hire and retain the best from every background and community.

ACM: Lear is a global leader in automotive seating & electrical systems production, with multiple production lines. Which production line is present in Macedonia and what specifically are you producing?

Capkovic: Lear Corporation Macedonia is part of the automotive seating industry, containing production lines for surface material production. We produce all types of car seat covers for different customers from the industry. The seat covers are made from fabric, vinyl and leather via a cutting and sewing process. Lear has been a world class cut & sew supplier of automotive trim covers for over 42 years. We produce everything from entry-level basic trim covers to high-end tailored trim for over 200 vehicle models globally and are the only seating supplier in the world that is 100% vertically integrated in cut & sew, leather, fabric and lamination. Our vertical integration capabilities enable us to control costs, reduce timing, and improve quality to service our worldwide customers. Vertical integration also allows for synergistic materials engineering to optimize performance, craftsmanship and cost.



ACM: We understood that you were analyzing other countries in this region as potential investment locations. What was the main reason behind your decision to pick Macedonia?

Capkovic: Due to the need to add capacity and satisfy Lear customer growth, Lear initiated a selection process, taking into consideration various suitable countries in Eastern Europe and North Africa. We analyzed factors such as the availability of the labor force, manufacturing and logistics cost, and a supportive environment for implementing and running a business; based on intensive research, Macedonia was selected as the preferred country for a new Lear production site. Additionally, our analysis showed that based on textile industry experience, available labor force and other factors, the TIDZ Tetovo location was ideally suited to supply our car manufacturing locations in Eastern Europe.

ACM: What are your early impressions on the business climate in Macedonia and how do you assess the cooperation with Macedonian institutions?

Capkovic: Being present for almost one year in Macedonia, we have positive early impressions regarding the business climate. Taking in consideration the

experience as a Fortune 200 company, we have identified many positive developments along with some areas for improvement, which are common for this stage of development. The State institutions have been cooperative and supportive throughout the implementation of our investment project. Being eager to attract foreign investment, they are open to understanding the needs of international companies and meet the specific requests of an industry/sector.

ACM: What are the projections for volume production and exports this year? Are there any plans for further expansion of the capacity of LEAR’s TIDZ Tetovo Plant?

Capkovic: In the middle of the launch phase, the production in the Greenfield factory until the end of the year is planned to reach 3000+ car sets per week. Full capacity of the Lear Tetovo Plant is planned to be achieved by year end 2017 and by then we expect to employ close to 2,000

ACM: Do you cooperate with domestic suppliers of goods and services; if yes, how would you rate this cooperation?

Capkovic: Whenever there is a possibility, we try to cooperate with domestic suppliers, since usually they can offer more competitive prices. As a result, we have established solid relationships with a number of domestic, even local, suppliers. There are some areas though – quality and consistency of provided services – that need upgrading and we are working hard on educating the local market to be able to follow our global standards and grow together.

COMPANY PROFILE

Lear Corporation is ranked #154 on the Fortune 500 with world-class products designed, engineered and manufactured by a diverse team of talented employees. As a leading supplier of automotive seating and electrical, Lear serves its customers with global capabilities while maintaining individual commitment. With headquarters in Southfield, Michigan, Lear maintains 240 locations in 36 countries around the globe and employs approximately 136,000 employees. Lear is traded under the symbol [LEA] on the New York Stock Exchange.

*Why is big pharma leaving Macedonia?
Continued from page 17*

But, the lower the level of a country’s economic development, the lesser the capacity to support treatment with innovative drugs. The question is: How to increase the presence of these drugs on the State Fund’s Positive List?

Proposals by pharmaceutical companies

The Association of Representatives of foreign manufacturers of innovative medicines, Farmabrend Nova, suggests a few possible solutions to increasing patients’ access to new drugs:

- a) Budget savings from price reductions to be invested in new innovative medicines;
- b) Openness to make agreements between the Ministry of Health, the Health Insurance Fund and companies in the interest of patients (currently being done at Medicines Agency);
- c) Create additional funding sources (the so-called health denar) to increase the percentage of the budget that is spent on drugs.

Farmabrend Nova representatives emphasize that within the EU, the process of revising the positive list ranges between 85-365 days. In Bulgaria, for example, if a drug is on the positive list in 5 EU countries, it is automatically added to the positive list.

According to Farmabrend Nova: “The process of revision and expansion of the positive list in our country was stopped until last year when a hemato-oncological drugs commission was established. After many years, this is a positive signal for innovative companies and their plans of registering new medicines in Macedonia.”

THE WORLD BANK RECOMMENDS



WITH THE SAVINGS FROM THE COST REDUCTION, YOU CAN BUY MORE EXPENSIVE INNOVATIVE DRUGS

A World Bank report on the spending of public finances, in its health section, recommends that Macedonia continue reducing the cost of procuring generic medicines through reference pricing and its public procurement system, while simultaneously introducing innovative approaches to procurement of expensive, new drugs. The Ministry of Health and the Health Insurance Fund will have to rely on cost-benefit analysis in terms of adding expensive treatments, procedures and new patented drugs on the positive list, through the Health Technology Assessments (HTA) process or similar mechanisms. It takes a long time to develop an HTA capacity program, so the World Bank recommends using modified methodologies taken from developed countries (Britain or Germany, for example) as a good temporary choice,” says the World Bank.



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NEW MEMBERS

Lynx Resources



Lynx Resources was established in November 2015 by Fusion Capital and Orion Mine Finance to acquire the SASA zinc/lead/silver mine in Macedonia.

The SASA mine is one of the largest operating zinc/lead/silver mines in Europe, producing concentrates containing approximately 30,000 tonnes of lead, 22,000 tonnes of zinc and 400,000 ounces of silver per annum.

Lynx Resources operates in line with leading industry practices for safety, environment and sustainability. The company strategy is to grow further through acquisitions, exploration and development.

FOD Novaci



FOD Novaci's main business activity is development and repair of steel parts. It was established mainly for helping the functioning of the largest power plants in the country. It has a specific strategic location and exclusive machines with robust ranges. FOD Novaci is ISO 9001:2008 certified, operates according to Macedonian laws and follows the European and International standards in order to create high quality products.



AmCham Macedonia has launched the “Companies Giving Back in Macedonia” database. This tool highlights the positive and proactive role that many businesses play in Macedonian society. All of our patron members and many of our other members are included in the database, since they lead the way in establishing best practices and increasing the impact of corporate social responsibility (CSR) programs and activities in the country. Already, certain trends can be seen, such as that the

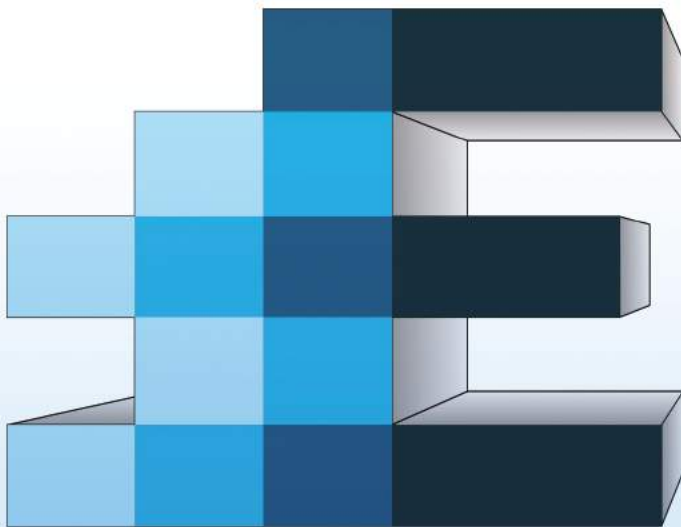
vast majority of 2015-16 CSR initiatives were donations given in the category, “Investment in the Community”. Just 3.5% were initiatives classified as “Environment”; 6% “Customer Relations”; 7% “Employee Relations”; and 11% “Education”.

The goal is to create a truly representative and national database, so non-member companies are also encouraged to send us details on their activities. Together, we can build a platform where we can share, inspire and improve our communities together!

ECOTIP

Ecotip Ltd. Skopje is established in 1998 in partner relations with Ecotip Ltd. from Republic of Slovenia.

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SCHIKI

Throughout the year, the AmCham Executive Office staff helps university students from low income households gain access to internship opportunities in our member organizations. Students simply need to submit a completed form and evidence of their low income status, then we do our best to find an internship that suits their interests and needs.

OPEN A DOOR

SUCCESS STORIES



INTERNSHIP

PROGRAM

HIGHLIGHTS

CURRENT PLACEMENTS

Natalija Mejandzieva – Internship Experience - EVN Macedonia

“ The reason I accepted to be an intern at EVN Macedonia, is that the company is reputable and one of the best employers in the country. This internship allowed me to gain experience, sharpen my skills and meet many new people. Soon after finishing with my internship, I received an offer for full-time employment from the Head of the Department, which I gladly accepted. At the moment I work in the Human Resources Department. The internship opens doors, you gain experience, you are able to make an impression and secure a greater chance of employment. That is why I am recommending it to everyone!



Aleksandar Velkoski - Internship Experience - SEAVUS

Andrea Mitevaska – Roche Macedonia - Internship Experience

“ Being able to work in Roche Macedonia - one of the leading pharmaceutical companies is a dream come true. I am very happy with the whole experience and how everything unfolded. I did my internship for 3 months, and afterwards I was offered a full-time employment. Currently I am working as a Study Start-Up Specialist. I encourage everyone to take on an internship opportunity, to put their knowledge and skills to the test, gain valuable experience and see how theory is being applied in the “real world”.



Ramadan Kurtishi - Internship Experience - Wabtec

SKOPSKO SMOOTH TASTING HOSTED BY PIVARA SKOPJE, ECOTIP & AMCHAM



Jovan Radosavljevic, Pivara Skopje

AmCham Patrons, Pivara Skopje & Ecotip, celebrated the successful installation of the first cold filtration system in the Balkans by hosting a unique event for AmCham's Corporate Members that took place at Pivara Skopje HQ. The event included a tour of Pivara's factory, guided by Brewmaster, Kirco Stojanov, a tasting of unpasteurized beer, as well as great food and live music fit to accompany the star of the show: Pivara's new brand, Skopsko Smooth.





Marija Stavreva
and Ioannis Geroulanos, OKTA



From the left Jovan Radosavljevic, Pivara Skopje;
Mr. Diomidis Nikolettopoulos, Stopanska Bank;
Stefan Peter, EVN Macedonia



From the left Kirco Stojanov, Pivara Skopje; Giovampietro
Ferrara, Pall Corporation; Ilija Andreevski, Ecotip





From the left Stefan Peter, EVN Macedonia and Jovan Radosavljevic, Pivara Skopje



PWC ACADEMY PRESENTATION

On May 31st a number of member representatives in HR and training roles joined us for a M2M learning session featuring a presentation of PwC Academy programs by Aleksandra Kuzmanovska, Manager, Audit & Assurance at PricewaterhouseCoopers. The group heard a brief overview of the PwC Training Academy program; mini MBA Program; the Certificate in Human resource Management (CIPD); and their Soft Skills Program. Ms. Kuzmanovska explained the programs were currently being offered in Belgrade, however, they were planning to begin offering them in Skopje later this year. The group openly discussed their organizations' training needs, the current offer on the local market, as well as the importance of being able to show a tangible return on investment for all training costs.



M2M INFO SESSION – AN INTRODUCTION TO PLATI BRZO WITH TIMUR SHOMANSUROV, GENERAL MANAGER



At this session, a number of members from the financial services industry had a chance to learn more about Plati Brzo's innovative payment solution, PayNet, and how it meets a clear need due to cash usage trends in Macedonia. The group also discussed the country's new Payment Services Law and its likely impact on the industry.

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 EVN Macedonia, Inc. Skopje
 Makedonski Telekom, Inc. - Skopje
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 Okta Crude Refinery Oil, Inc. Skopje
 Pivara Skopje, Inc.
 Skopski Pazar, Inc. - Skopje
 Wabtec MZT, Inc. Skopje

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