

Legislative & Policy Journal

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Announcements

This Week:

- *October 24: „Day of Great Plans“; Zagreb, Hotel Westin*
- *October 25-26: „International Investment Forum Dubrovnik 2012“; Dubrovnik, Hotel Palace*
- *October 25-27: „Greenvest: Invest In Green Croatia“; Zagreb, Esplanade Hotel Zagreb*

ZAGREB, OCTOBER 22, 2012

ISSUE 007

WEEKLY TOP HEADLINES

PHARMA

FDA Visits Pliva Factory: Preparing for U.S. Biosimilars Market?

In August, the US Food and Drugs Administration (FDA) carried out their inspection of Pliva's Generic and Biogeneric production facilities in Zagreb and in Savski Marof, near Zapresic. The inspection control passed successfully, determining if the

importance in Pliva's business development strategy.

Due to various reasons, including lobbying by innovative drug companies and the conservative policies about the use of organic materials in R&D, including the



PLIVA ZAGREB HQ

production facilities satisfied the strict global requirements for the production of pharmaceutical products. This is a regular visit by a drugs regulator of a country in which Pliva sells its pharmaceutical products. Taking into account the manner in which the biosimilars (biogenerics) market is developing in the United States, this visit by the FDA and their positive report gains a wider

production of medicines, biosimilars are not permitted on the US market, meaning that innovative biopharmaceuticals have exclusivity. Due to the high cost of health care and the reform of the health care system in the US, deregulation of biosimilars in the US is in process. The introduction of biosimilars to the US market is set for 2014. Some studies estimate that the US biosimilars market could be

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WEEKLY TOP HEADLINES

valued at \$9 billion (USD) by the end of the decade. The global biopharmaceutical market is valued at \$138 billion in 2011 and expected to grow to over \$320 billion by 2020. Therefore, the FDA's approval of Pliva's biosimilars production facility in Savski Marof is a significant step in Pliva's business development strategy towards the US market for 2014 and beyond.

In 2006, Barr Pharmaceuticals acquired Pliva, primarily due to the synergy between the two companies. Barr was lobbying for the deregulation of biosimilars in the US, but did not have any experience in the production of biopharmaceuticals. Pliva had production experience and production facilities in Croatia and in other European countries. The purchase was strategically profitable both for expanding into Europe and for the future US biosimilars market. In 2008, the global generics company from Israel, Teva, acquired Barr and, subsequently, Pliva. Due to Teva's experience in biopharmaceuticals and network in the US and Europe, it was questionable what Teva's strategy would be towards Pliva. The expansion of Pliva's Savski Marof production facilities and the FDA certification are sound evidence that Pliva is an integral part of Teva's European and US business strategy.

Motorway Concession Advisor – 8 Bids Received

The Transportation Ministry received the bids for the motorway concession advisory services for the Croatian Motorway Company (HAC) and the Rijeka-Zagreb Motorway (ARZ). The 8 bidders include: joint bid Goldman Sachs and InterCapital Securities; joint bid Erste Group Bank, Deloitte Consulting Services and Wolf Theiss Rechstanwaelte; joint bid Lazard Freres and Watson Fairley & Williams; joint bid Zagrebacka Bank and J.P. Morgan; N.M. Rothschild & Sons; BND Paribas; Macquarie Capital (Europe); joint bid Bardek, Lisac, Mucec, Skoko, Sarolic Law Firm, CMS Reich-Rohrwig Hainz Rechtsanwaelte, Zagreb Institute of Economics. The bids for financial, legal, technical and marketing advisory services range in monetary value from €6.6 million (Erste, Deloitte, Wolf Theiss) to €11.4 million (Goldman Sachs, InterCapital). The Government is expected to award the job within 45 days.

Swedish Securitas Becomes Leading Security Services Competitor

In August 2011, the Swedish security services company Securitas acquired 85% ownership of Zvonimir Security in Zagreb. They have also acquired the Croatian security companies Protect (Rijeka) and Security Buzov (Slavonski Brod). Securitas is a global securities company, employing over 300,000 in 51 countries. The Croatian security services market is valued at €200 million, which is expected to rise with the entrance into the EU and increased trend of outsourcing of services by the Croatian police.

Croatian Wood Processing Companies Seek Strategic Investors

The Croatian wood processing cluster of companies announced their search for strategic investors in ten projects/companies, valued at €30 million. The projects primarily entail companies in receivership or looking for strategic international investors. One project is the Delnica Energy Production facility looking for a strategic partner for a biomass plant valued at €7 million. Another project is Biokalnik Drvo and is in receivership, going on auction next month for an asking price of €12 million.

Maraska New Natural Gas Consumer of ENV Network

Natural gas concessionaire EVN Croatia, owned by the Austrian energy company EVN AG, connected the soft drinks producer

Maraska to its natural gas network. They built a 30-km natural gas network in the Zadar County, with plans to build another 60 km. EVN was awarded 30-year management concessions for the Zadar County (2009), Sibenik County (2011), and Split County (2011), planning to install a pipeline network of 1,450 km, valued at €100 million.

PharmaS Generics Expansion Continues

The Croatian generic pharmaceutical producer PharmaS, owned by Luka Raic, owner of the Lura Group, is opening a new production facility in Serbia. The factory is located in the Zrenjanin industrial zone, valued at €11 million. In Q1 2012, PharmaS Serbia was named the fastest growing pharmaceutical company in Serbia.

Croatian Telecom and Vipnet Send Offers for 4G Network

The telecoms operators Croatian Telecom (HT) and Vipnet sent offers to Croatian Post and Electronic Communications Agency (HAKOM), replying to their tender for licensing rights for the development of the digital LTE/4G network. Each operator is required to pay €20 million to the state and €480,000 to HAKOM for the operating rights. It's believed that the operating fees will compensate for the lost revenue from the 6% mobile phone services tariff, which was lifted due to legislation discrepancies with EU regulations. The third national operator in Croatia, Tele2, has chosen not to participate in the tender.

Deputy PM Cacic Announces Road Show for Croatia Electra Bonds

First Deputy PM and Economy Minister, Radimir Cacic (HNS), and the CEO of Croatia Electra (HEP), Zlatko Koracevic (HNS) confirmed this week that they will be going on a "road show" to sell HEP bonds, whereby the state-owned company intends to collect between €300 million and €500 million.

Croatian National Bank: FDI Down

The Croatian National Bank (HNB) published its Q1/Q2 2012 FDI figures totalling €154.4 million, which is on fourth of the FDI figures for the first half of 2011. Austria, Turkey and the Netherlands are the countries of origin for the largest investments. Germany and Hungary registered the largest statistics for divestments.

Croatian Defense Minister Meets U.S. Secretary of Defense

Secretary of Defense Leon Panetta hosted an honor cordon to welcome Croatian Defense Minister Ante Kotromanovic (SDP) to the Pentagon October 17. The two held talks on a host of issues of mutual interest, including defense cooperation. "The secretary commended the minister on making progress across Croatia's defense modernisation priorities amidst the financial crisis and for Croatia's regional leadership in Southeast Europe," said acting Assistant Defense Secretary for Public Affairs George Little. Little said Panetta recognised Croatia's continued commitment of forces to NATO's security mission in Afghanistan.

President and PM in Brussels

Prime Minister Zoran Milanovic (SDP) and President Ivo Josipovic (SDP) were in Brussels participating in the meeting of heads of state and government of European Socialists and the Council of Europe. Josipovic met with the President of the European Parliament, Martin Schulz. After the meeting, he stated that Croatia's EU membership is not in question and that Croatia will fulfil the remaining membership requirements.

• Public
Debate

◊ Government
Cabinet

▪ Sabor-Urgent
Procedure

▪▪ Sabor-1st
Reading

▪▪▪ Sabor-2nd
Reading

LAWS TO WATCH:

◊ **Government Decision for State Aid Supporting Risk Capital SME Investment and Decision on Regional State Aid**

Proposed by: Ministry of Finance

Measures for risk capital investment into SMEs are increased from a maximum level of support of €1.5 million yearly to €2.5 million yearly. State aid support for regional development projects over €50 million will be determined on an individual basis, taking into account all positive and negative effects of every specific case.

◊ **Government Order on Emission Levels of Contaminated Substances from Immovable Sources**

Proposed by: Ministry of Environment and Nature Protection

The order defines regulations for emission levels of contaminated substances, monitoring and evaluating emissions, registration of data in the ministry, warehousing facilities for organic waste, and means of reducing emissions. The order also defines reporting and deadlines for reporting to the Agency for Environmental Protection and the means of delivering data to authorised EU regulatory bodies, including permitted reporting after deadlines during the alignment and transition period.

REGULATORY NEWS:

Croatian Post and Electronic Communications Agency (HAKOM)

▪ **“Hakometer” – Certified Internet Speed Software**

HAKOM presented their certified software, “Hakometer”, which measures the speed of broadband internet. The software is free and has been publicly available since 5 October. The fact that this software is certified by HAKOM means that the statistics provided by the software can be used as evidence by consumers in their complaints towards operators. HAKOM regulations require operators to contractually define the speed of their internet broadband package and also publicly advertise their available broadband speeds, minimum speed in relation to their maximum advertised speed. This software becomes a tool to supervise operators.

SABOR WEEKBOOK:

Current and Future Event Listings from Parliamentary Committees

Personnel: Committee for Internal Policy and National Security approved the nomination of **Dragan Lozancic** as Head of the Security and Intelligence Agency (SOA), the national intelligence agency in Croatia.

Parliamentary Activities: **Andrej Plenkovic (HDZ)** participated in Berlin at the conference on the influence of Croatia's EU membership on the countries of SouthEast Europe. ◊ **Milorad Popovac (SDSS)**, Chairman of the Committee on Foreign Affairs, presided over the initial meeting of foreign affairs parliamentary committee chairs from Croatia, Serbia, Bosnia-Herzegovina, and Montenegro.

Plenary Session: The following laws were ratified: Energy Act, Law on Energy Business, Law regulating the Center for Monitoring Business Activities in the Energy Sector and Investments, Law on agricultural and regional development state aid (*all legislation detailed in previous issues of L&P Journal: Laws to Watch; for further details contact L&P Journal staff*) ◊ The Sabor reviewed and approved the 2011 States Attorney Report presented by Attorney General **Mladen Bajic**.



invest in
**DUBROVNIK
NERETVA
REGION**

**International Investment Forum
Dubrovnik 2012**

Friday, October 26, 2012
Hotel Dubrovnik Palace - Dubrovnik, Croatia



PARLIAMENTARIAN ON THE MOVE:

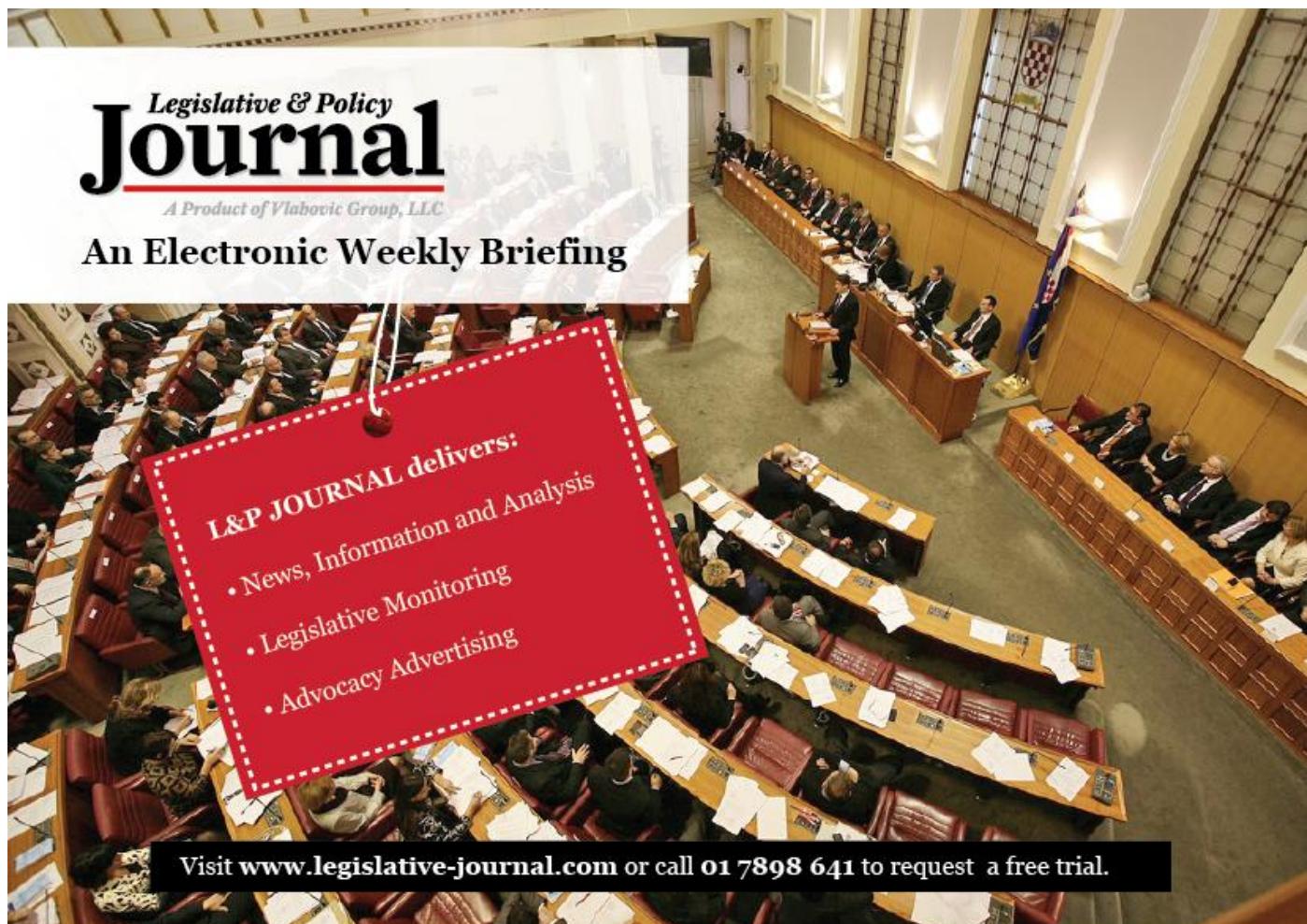
Andrej Plenkovic



ANDREJ PLENKOVIC, CROATIAN OBSERVER IN EP

Andrej Plenkovic has been active this past week in his duties as EU parliamentary observer. He presided over the common parliamentary committee, Croatia-EU, held in the European Parliament in Brussels, addressing various issues affecting Croatia and the EU, including the recent EU Monitoring Report on Croatia. He also participated at the conference in Berlin addressing Croatia's upcoming EU membership and the impact membership would have on the countries of SouthEast Europe. Plenkovic is a Croatian MP and is considered to be an expert on EU issues with 18 years of diplomatic experience. Born in 1970, he completed his law degree in 1994 and began his professional career at the Ministry of Foreign Affairs. In 1999, he took the position of advisor to the Minister of Foreign Affairs for EU affairs. In 2002, he was the Deputy Chief of Mission of Croatia in Brussels. In 2005, he was named the Deputy Ambassador of Croatia to France. In 2010, he was named the State Secretary for EU Integration at the Ministry of Foreign Affairs. In 2011, he became a member of the Croatian Democratic Union (HDZ)

and was elected as an MP to the Croatian Sabor. During the HDZ internal elections, he was a candidate for party leadership in alliance with former Prime Minister Jadranka Kosor, who lost the elections for party president to Tomislav Karamarko. Plenkovic's EU expertise is only recently being utilized by the new HDZ leadership. As a European Parliament (EP) observer, Plenkovic would be a natural candidate for the EP elections in May 2013, which will depend upon his status within his own party.



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EU AFFECTING BUSINESS

• TELECOMMUNICATIONS: EU Membership Drops Roaming Pricing

As of Croatia's EU membership on 1 July 2013, the pricing for roaming telecoms services will drop. Even though Croatia's telecoms legislation is fully in line with EU regulations, the telecoms market is not fully liberalised and the telecoms operators are not in a hurry to adjust their pricing. Presently, the pricing for roaming services is up to 7 times more expensive than in the EU for telephone services and up to 12 times more expensive for data transfer services. With Croatia's EU membership, pricing for roaming services will need to be adjusted to within EU norms. Operators will need to adjust their pricing to charge for the first 30 seconds of a service and afterwards to charge by the second. Consumers will be allowed to directly decide upon their international roaming services provider, which will spark additional competition among operators.

• ENVIRONMENTAL PROTECTION: IPPC Directive – Challenge for Croatian Industry

Croatia's EU membership will require Croatian companies to adjust to EU norms in all areas, including environmental protection. Approximately 200 Croatian companies will have to adjust their industrial and production operations to comply with the IPPC Directive - Integrated Pollution Prevention and Control (2008/1/ EC) or else they would be forced to shut down their production. Ecological permits are issued by the Ministry of Environment and Nature Protection, but the final decision is made by the EU and the European Commission (EC). Environmental permits must be reviewed and issued every 5

The Croatian Post and Electronic Communications Agency (HAKOM) has already adjusted pricing to the EU average for large consumers and business consumers; HAKOM's role and influence as market regulator is expected to increase with EU membership. EU membership will result in the adjustment of business management operations for telecoms operators in Croatia, approximately 50 companies. The three largest national telecoms companies are Croatian Telecom (HT), owned by Deutsche Telekom, Vipnet, owned by Austrian Telekom, and the Swedish Tele2; their revenues for 2011 equalled €1.1 billion, €405 million, and €135 million, respectively.

years. Presently, approximately 100 companies have applied for permits, including larger producers such as sugar producer Viro and the Karlovacko brewery. During the EU negotiations process, some large companies such as INA, HEP, and Petrokemija were allowed a transition period until 2018, while other companies such as Cateks textile and Klana timber processing have a transition period until 2014. It is estimated that the cost of adjusting to environmental requirements will also require an investment of up to €2 billion. Companies that will not be able to adjust to the new EU regulations will need to close operations.

PERSON OF THE WEEK

Nikola Dobroslavic, Dubrovnik-Neretva County Prefect

The Dubrovnik-Neretva County, led by Prefect Nikola Dobroslavic (HDZ), is the first county in Croatia to organise an international investment forum to be held on 26 October in Dubrovnik. The goal of the International Investment Forum Dubrovnik 2012 is to present and promote investment opportunities in the County to local and international investors interested in Dubrovnik, the County and the wider Southeast Europe region, welcoming numerous representatives of international and domestic companies, the Croatian Government and Ministries, EU representatives and local and regional authorities. Dobroslavic's commitment to advancing the economic development of his County is reflected by his recent statement: "We want to emphasise to investors that we are prepared to invest added effort and provide all the necessary support to realise projects of mutual interest. The County and I, personally, are at the disposal of interested investors to resolve all obstacles from urban planning issues to the coordination with other state, local and city authorities." The County is organising the Forum together with the regional development agency DUNEA, the Croatian Chamber of Commerce (HGK) and other partners. The Forum's panel discussions will address the final critical investment issues: tourism, business zones, agriculture, mariculture, energy, infrastructure development, EU funding.

Nikola Dobroslavic graduated from the Faculty of Philosophy, University of Zadar. He began his political career as the President of the Slano Community Board and later would become the Head of Slano in 1997 until 2001 and again from 2003 to 2009. In 2009, he was elected as the Prefect of the Dubrovnik-Neretva County.



NIKOLA DOBROSLAVIC, COUNTY PREFECT

LOBBYING

The First Ever Legislative Act to Regulate Influencing Decisions in Croatia

The government – whether it be the executive or the legislative branch – simply cannot know the intricate details of the myriad aspects of national life that its actions might affect unless it has access to the expert contributions of the persons and interests involved



JUDICIARY MINISTER ORSAT MILJENIC

Croatia will soon have a legislative framework to regulate the business of lobbying. The Ministry of Justice will be sending a draft of the Law on Lobbying for public debate this week. The law will allow everyone who is interested to professionally lobby the executive and legislative branch to publicly register, thereby provide their professional services transparently. The legislative framework will also allow the legitimate lobbying to move out of the “grey zone” and become a fully legitimate profession, in a way the newest profession in Croatia. The development of professional lobbying in Croatia began with the establishment of the Croatian Lobbying Association (HDL) in 2008. This NGO was established in order to educate the political and professional public about lobbying activities and how lobbying can be done in a professional and legitimate way. Since 2008, four Justice Ministers have changed and finally regulating lobbying has been recognised as an important tool in the development of the democratic institutions and also as important tool in the battle against corruption.

What Does the Law Bring?

The new law will require individuals and businesses that work to influence the executive and legislative arms of government and other regulatory bodies to register as lobbyists. Civil society organisations, such as NGOs will be exempt from this requirement. The law introduces a public register of lobbyists, the issuing of lobbying accreditations, yearly reporting of operations, lobbying contracts and defines a basic framework of behaviour for lobbyists. According to information from the Ministry of Justice, the legislation is planned to be ratified by the end of this year taking effect in January 2013.

The Impact on the Business Community

The law could become a crossroads for the business community in the manner in which they organise their lobbying activities and also because the law will raise the awareness of the importance and advantages of strategic lobbying in the protection of their

specific business interests. The EU integration process is pushing companies to monitor and position their interests according to new legislation and regulation; this is best seen within the tobacco and telecoms business sectors. Companies that want to profit from EU membership will need to lobby not only Croatian institutions, but will also be pressured to monitor decision-making in Brussels. Professional and strategic lobbying requires constant monitoring and intelligence of all policy and regulatory trends to avoid expensive surprises.

For example, the renewable energy sector is a dynamic industry in Croatia, but is poorly represented from a lobbying perspective; there are many similar examples. On the other side, big Croatian companies have not yet realised that it is important for the development of their businesses to monitor activities in Brussels. As a result, they do not have monitoring of dossiers (the European term for monitoring sector issues). Agrokor, TDR, Podravka, Duro Dakovic, HEP, Plinacro, and the Croatian Post are only several companies that need to define their post-EU accession strategies.

The Lobbying Law might serve as a catalyst for board members to analyse their present strategies and decide if they can continue to make informed business decisions without strategic lobbying as an integral part of that decision-making process.

Lobbying and Government

First of all, the government – whether it be the executive or the legislative branch – simply cannot know the intricate details of the myriad aspects of national life that its actions might affect unless it has access to the expert contributions of the persons and interests involved.

The Ministry of Justice should be applauded for their initiative to regulate lobbying in Croatia. Regulating lobbying is a challenge for every government in the world. The American experience shows that it is important to have mandatory registration and a quality supervision of lobbying activities. EU institutions still have a voluntary registration system, even though it is evident that the money spent on lobbying in Brussels grows from year to year. The Croatian Government has used lobbying services in the past and in the present, including various political issues (e.g. recognition of Croatia as a state, scheduling meetings with key political figures, EU relations, relations with The Hague Tribunal, etc.). The use of lobbying services is not irregular. Lobbyist firms are always used by government institutions, because of their political connections and knowledge of the decision-making process within the target institution.

In general, governments decide to enlist lobbyists (and attorneys) in delicate international relations situations. However, every government in the world is also the target of lobbyists, whether the interest of local municipalities advocating their communities or big business lobbying by financial and banking sector. The Lobbying Law is a good initiative and policy by the government, especially in the areas of strengthening state institutions and increasing transparency. The temptation to over-regulate should be resisted, since it results in the unwanted effect of avoiding registration. It still remains to be seen who will register as a legal representative of an interest group in Croatia.

TRADE POLICY

The Future Role of Government Trade Office

The attempt to institutionalise the Government Trade Office (DUTP) as the primary “spokesperson” for the Croatian business community in the EU, creating and implementing Croatia’s European trade policy is “too little, too late”

In the last couple of months, the Croatian Government has begun to have a proactive and partnership relationship with the Croatian Employer’s Association (HUP), instead of a confrontational policy which was predominant through the first half of 2012. Of course, this is a positive development, because cooperation with the business community is the only way to promote and realise badly needed investment. One area that they are attempting to cooperate is in the area of trade policy, especially in relation to Croatia’s EU membership and, hence, exit out of the Central European Free Trade Agreement (CEFTA). However, the attempt to institutionalise the Government Trade Office (DUTP) as the primary “spokesperson” for the Croatian business community in the EU, creating and implementing Croatia’s European trade policy is “too little, too late” and ignores the systematic gap in the business community’s advocacy efforts in the EU and EU Member States.

The European Commission requires new avenues and means of communications to address various EU policies. This attempt to make DUTP relevant can be viewed in this light. A recent HUP-sponsored media insert had an article promoting DUTP and actually citing their contact details – telephone, fax and website – for businesses to contact for DUTP to be their “spokesperson” in the EU. With Croatia’s scheduled to become a full EU member state in 8 months, it is unrealistic to believe that the Croatian Government and DUTP will be a relevant voice for Croatian businesses within the EU and individual Member

States. Unfortunately, the national trade associations (i.e. Croatian Chamber of Commerce (HGK), HUP, Croatian Association of Trade and Crafts (HOK), etc.) that should be addressing these issues have not prepared for this situation. HGK has an inefficient office in Brussels, but with a large budget due to mandatory membership, their international presence in strategic member states (e.g. Germany, Austria, France, UK, etc.) is non-existent. HOK’s organisation is old-fashioned and out of date with no semblance of an EU presence and, yet, they should be the voice of all SMEs. Actually, HOK recently decided to close their Brussels office.

DUTP is a state office, which means it is an office that reports directly to the Prime Minister’s Office. Without further explanation, the business community cannot depend upon the (non) efficiency of government bodies. The structural problem is not whether the Government will speak for Croatian business. The problem is more fundamental and it lies in the structural deficiencies of these organisations, in relation with the communication with EU institutions, EU bodies, EU agencies, and the institutions, bodies, and agencies of individual Member States. Therefore, support DUTP? Yes. Depend upon DUTP? No. The business community needs to increase and invest funds into their organisations to begin to proactively (even aggressively) lobby at the EU level. This is not a periodic initiative. This needs to be a daily activity by business associations and individual companies, which includes the use of professional experts and policy advocates who understand the institutional and political processes of the EU. Even when Neven Mimica as a designate Croatian EU Commissioner takes office next fall, he will not be able to resolve specific regulatory issues affecting Croatian business community. The time to engage in now.

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