

Guest Editorial: Miroslav Dubovsky of DLA Piper ■ Across the Wire: Deals and Cases in CEE ■ On the Move: New Firms and Practices ■ The Buzz in CEE ■ Marketing Law Firm Marketing: Not Enough Time ■ Comply or Die: The Rise of Compliance in the Balkans ■ Conference Countdown: An Interview with Sponsors About the 2020 Dealer's Choice Law Firm Summit in London ■ The GDPR in CEE: One Year On ■ Market Spotlight: Austria ■ Guest Editorial: Martin Brodey of Dorda ■ Austrian Law Firms - Behind the Benefits ■ Inside Out: Marinomed Biotech IPO ■ Expat on the Market: Emmanuel Kaufman of Knoetzl ■

■ Austrian Law Firms - Behind the Benefits ■ Inside Out: Marinomed Biotech IPO ■ Expat on the Market: Emmanuel Kaufman of Knoetzl ■ Market Spotlight: Albania ■ Guest Editorial: Rezart Spahi of Frost & Fire Consulting ■ The Belated Boom: Albania's Troubled Road Towards EU Accession ■ Experts Review: Pharma and Life Sciences ■



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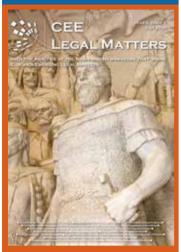


JPM

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NAGY $_{\&}$ TRÓCSÁNYI





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If you like what you read in these pages (or even if you don't) we really do want to hear from you. Please send any comments, criticisms, questions, or ideas to us at:

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Bit by bit, piece by piece, the parts come together. First, we decide to have next year's Dealer's Choice Law Firm Summit and Deal of the Year Awards Banquet in London. Then Slaughter and May agree to co-host Dealer's Choice. Then we open up sponsorship opportunities – one per country – to the law firms of CEE.

The pieces continue to slide into place. Avellum, from Ukraine, and Nagy & Trocsanyi, from Hungary, claim the sponsorship slots for those two countries. Then we lock down the date for the joint events next year – April 23, 2020 – and lock down the location – The HAC in the center of London (the HAC is the London home of the Honourable Artillery Company, a charity incorporated by Henry VIII in 1537 whose primary charitable purpose is the support of the Regiment which bears its name). The Adriala Business Law Firm Alliance in South-East Europe signs up as a sponsor, then JPM Jankovic Popovic Mitic signs up as a sponsor for Serbia.

Other puzzles begin to take shape as well. We lock down our 2019 schedule of local/country-specific GC Summits as well, with the Hungary GC Summit scheduled for Budapest on October 1, the Balkan GC Summit scheduled for October 10, 2019. We also announce plans for next year's regional GC Summit, scheduled for Budapest in May 2020. Sponsorships for those events are being finalized now – though a number of valuable slots remain as I write this, so if you'd like to help us complete that particular puzzle, please let me know.

Our own "puzzle" continues to take shape as well. We were joined earlier this year by Staff Writer Andrija Djonovic, who contributed an article on Compliance in the Balkans to this issue (see page 30) as well as several Buzzes (see page 20) and whose contributions to the CEELM website have



been significant since the day he joined. We will also be joined in July by our new Content and Events Associate, Agnieszka Januszczyk, who will be overseeing our in-house content and contacts and helping organize CEE Legal Matters' in-house events. More significant changes to our office are expected soon as well.

We even, more or less, resolved our conflict with the self-appointed supervisor of the building our office is located in about our air conditioning system, which is simply critical during Budapest's increasingly brutal summer months in our office space with windows directly onto the sun. That, I suppose, was less a puzzle than a battle, but success was just as important.

Ultimately, with Dealer's Choice and next year's DOTYs taking shape, the long-awaited launch of our unique-in-the-world online directory (connected to the CEELM content and database) only weeks away, and the CEELM magazine and website both continuing to grow in reach and reputation ... things are going well.

It takes time, doesn't it? Putting together complicated puzzles?

David Stuckey



I am often asked by my foreign colleagues and clients about how the Czech Republic is doing, and my answer is that we are doing fine. Putting aside the political situation, which is similar to many other countries, economically we are doing very well; there was strong GDP growth of 4.6% in 2017 and almost 3% last year. Part of this growth is clearly attributable to our strong, maturing startup and investor community, which is pushing the country forward. Czechs have a talent for improvisation and finding solutions that work well, using innovation, research and development, and technology. We have invented many tools that have changed the world in fields such as nanotechnology, chemistry, and engineering. At the same time, we now have a pool of investors who are able to invest in new startup companies and back up the research and development that is done.

What is my perspective of the situation on the Central and Eastern European markets and in the Czech Republic? My view is that it is an area of great opportunity, especially if we look at human capital. As a whole, Central and Eastern Europe countries usually do very well and grow above the EU 28 average in terms of GDP. Only a handful of countries in this region grew less than 4% in 2017. Despite the language challenges, all of them have proven to be interesting places for expansion of foreign companies. Slovakia - together with the Czech Republic - is a regional powerhouse in regards to the automotive industry, which is also growing (along with other forms of manufacturing) in Hungary and Romania. The contribution of international companies to these four countries in value-add is more than 40% showing their openness towards international capital. Poland with its large population is quickly gaining strength as a business and investment hub. Austria is considered a top innovator - more than 3% of its GDP is spent on research and development.

If we look at Czechs specifically, they may have a rather conservative approach in many areas, but not in doing business. Czechs are used to doing things on their own – using their initiative and creating ingenious solutions. Let me illustrate this pioneering spirit with two stories of examples we were fortunate enough to be involved in.

My colleagues at DLA Piper and I have recently been working on a very interesting acquisition deal. A Czech game developer startup called Warhorse Studios was acquired by THQ

Nordic, a big international game publisher. The game studio was founded just a few years before the EUR 33.2 million acquisition. Warhorse Studios founder, Daniel Vavra, is a good



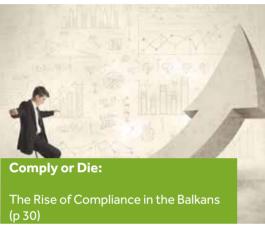
representation of what I call the Czech approach. He was a very experienced game developer but he had a dream of creating a new, disruptive, game that would change the rules of the genre. He was persistent enough to convince potential investors that his project, a game called Kingdom Come Deliverance, would be successful. However, before investing, they set him a challenge: to crowdsource enough money to start the development of the game. Only when he reached this target they would invest in the project. He raised – and exceeded – the required amount. As a result, investors provided the promised financial support, and a few years later the game became a huge success, with over two million copies sold.

Another good example is Kiwi.com. A majority stake of this successful travel search engine has recently been acquired for about USD 215 million by private equity firm General Atlantic, in a deal that converted Kiwi.com into a truly global company. At the beginning, Kiwi.com started with the simple assumption that things could be done differently and better. Its founder, Oliver Dlouhy, was not satisfied with how travel and air ticket search engines worked, so he and a small team of developers from South Moravia created a new project which has since grown tremendously. It was his stubborn approach and vision that led to this success.

As is usually the case, the most valuable investment is in smart people – in those with potential, who can transform ideas into great things, projects, and services. And I am lucky and privileged that we have an abundance of such people in my country – and in our Prague office. We have experienced lawyers who are not afraid to go the extra mile and deal with any issue. They are not afraid to challenge themselves, gain new knowledge and skills, and assist amazing clients (not only those mentioned above) on their way to success. And this is not only great news for the office but also for the country.

Miroslav Dubovsky, Partner, DLA Piper Prague PRELIMINARY MATTERS









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JULY 2019 ACROSS THE WIRE



FEATURED DEALS JULY 2019

Avellum Advises on Sale of Stake in Dobrobut to Horizon Capital



Avellum advised Dobrobut and its shareholders on the sale of a minority stake in the company to Horizon Capital.

Dobrobut is a network of clinics and medical institutions in the Kyiv region of Ukraine. The company invests in digitalization of business processes, including a mobile platform that allows patients to plan and pay for their visits online. According to Dobrobut CEO Oleg Kalashnikov, "as a result of this transaction, Dobrobut will provide even more types of high-quality health-care services. Opening of new clinics will allow us to become closer to our patients, while the provision of unique services will let us master new skills. The support of our reliable partners will allow the fulfillment of Dobrobut's most ambitious plans, aimed at the improvement of people's health."

Horizon Capital is a private equity firm in Ukraine, backed by over 40 institutional investors in four funds. The firm is led by its Founding Partners Lenna Koszarny and Jeffrey Neal and Senior Partner Denis Tafintsev.

"This transaction is a good sign for the Ukrainian economy in general and the Ukrainian healthcare industry in particular. Readiness of the reputable private equity fund and investors to enter such a sophisticated business signifies Ukraine's huge potential for growth. We are convinced that this deal will bring most fruitful results to our customers, who are the primary stakeholders in Dobrobut business. We are grateful to Avellum for helping us to negotiate and resolve complex legal matters during structuring and implementation of this deal."

- Inna Koval, Counsel, Dobrobut

The Avellum team was led by Partner Yuriy Nechayev and included Partner Vadim Medvedev and Associates Anton Arkhypov, Dmytro Symbiryov, Uliana Lutchyn, Maryna Buinytska, Alina Zagatska, Dmytro Tkachuk, Anton Zaderyholova, and Oleksandr Kulykovskyi.

Sayenko Kharenko advised Dobrobut on the deal.



PRK Partners Advises Remy Cointreau Group on Sale of Czech and Slovak Distribution Companies to Mast-Jagermeister



PRK Partners advised the Remy Cointreau Group on Czech and Slovak aspects of the sale of its Czech and Slovak distribution companies to Germany's Mast-Jagermeister.

The deal was closed in April 2019 and financial details were not disclosed.

The PRK Partners team consisted of Partner Jan Kohout and Associates Shiyang Zhang and Marian Baus.

Germany's Luther law firm provided advice to Remy Cointreau Group on German elements of the deal and Germany's Gutt Olk Feldhaus and Schoenherr's Czech and Slovak offices reportedly advised Mast-Jagermeister.



ATTORNEYS AT LAW

JULY 2019 ACROSS THE WIRE

Wolf Theiss Advises on XXXLutz Acquisition of Kika's CEE Business



Wolf Theiss advised XXXLutz on the merger clearance process in relation to its acquisition of Kika's Eastern European from SignaRetail.

The parties signed the contracts for the sale of 22 locations in the Czech Republic, Hungary, Romania, and Slovakia on April 26, 2019. The transaction included both the operational retail business with over 1,500 employees and the 22 properties.

XXXLutz Group is a global furniture retailer founded in Haag am Hausruck in 1945. The company has more than 260 stores in Austria, Germany, Czech Republic, Croatia, Switzerland, Romania, Sweden, Slovenia, Slovakia, Bulgaria, and Hungary.

Signa Group is a privately managed European holding company focusing on real estate, retail, and media sectors. Its portfolio of assets is valued at over EUR 14 billion.

The Wolf Theiss team was led by Partners Markus Bruckmuller, Christian Mikosch, Peter Oberlechner, and Eva Spiegel and also included Partners Janos Toth, Luka Tadic-Colic, Niklas Schmidt, and Claus Schneider, Counsels Katarina Bielikova and Matthias Schimka, Senior Associate Jiayan Zhu, Associates David Gschaider, Lukas Pinegger, Peter Ihasz, Ivana Hovancova, Iris Riepan, Jakob Jelinek, Natascha Johannik, Stefan Horn, Marlene Bouzek, and Lucia Mocibob and Consultant Melanie Dimitrov.

XXXLutz was also represented by CHSH on the purchase. Noerr, together with the Austria's Arnold law firm, advised Signa-Retail on the sale of Kika's Eastern European business to XXX-Lutz.

WOLF THEISS

Schoenherr Advises on Tele2 Croatia Sale to United Group



Schoenherr advised Tele2 AB on the EUR 220 million sale of its Croatian business, Tele2 Croatia, to the United Group.

Closing, which remains subject to approval from the relevant regulatory bodies, including the Croatian Competition Agency, is expected before the end of 2019.

Swedish telecommunications group Tele2 was founded in 1993. The company has been listed on Nasdaq Stockholm since 1996.

The United Group, which is headquartered in Amsterdam, is a connectivity and media provider in South East Europe. It has network coverage in the region with 3.82 million subscribers and offers local and international content. The United Group has operations in six countries.

Kirkland & Ellis and Divjak, Topic & Bahtijarevic represented the BC Partners-backed United Group.

JPM and Karanovic & Partners Advise on Pepsico and Karlovarske Mineralni Vody Acquisition of Knjaz Milos



JPM Jankovic Popovic Mitic advised Pepsico and Karlovarske Mineralne Vody on the acquisition of Knjaz Milos, a producer of mineral water and soft drinks in the countries of former Yugoslavia, from Mid Europa Partners. Karanovic & Partners advised Mid Europa Partners on the sale.

The deal is expected to close in the third quarter of 2019 upon issuance of relevant merger approvals.

DEALS SUMMARY JULY 2019

"JPM was delighted to contribute to the successful acquisition of the Serbian beverage flagship by our clients. We have all been excited to cooperate with the exceptional team of advisors during the last couple of months and are looking forward to successful completion. Knjaz Milos is well-known to JPM since we previously advised Salford Capital Partners during both the privatization and exit from this investment. During this period JPM also advised Knjaz Milos and I had the pleasure to serve as one of the members of the Board of Directors."

Nenad Popovic, Senior Partner,
 JPM Jankovic Popovic Mitic

The JPM team was led by Senior Partner Nenad Popovic and included Partners Jelena Stankovic Lukic, Nikola Poznanovic, Ivan Petrovic, Bojan Sunderic, and Jelena Nikolic, and Senior Associates Stefan Jovicic, Bojana Javoric, Anja Sakan, and Jelena Otasevic.

"Since Knjaz Milos is one of the most reputable and recognizable brands in Serbia, it was a privilege to be involved in this complex transaction. Congratulations to Mid Europa Partners and the other stakeholders on its successful completion."

 Milos Jakovljevic, Partner / Independent Attorney at Law in cooperation with Karanovic & Partners

The Karanovic & Partners team included Partners Rastko Petakovic and Milos Jakovljevic and Associate Sava Draca.

White & Case worked alongside Karanovic & Partners in advising Mid Europa Partners on the sale. Clifford Chance and Kocian Solc Balastik worked alongside JPM in advising Pepsico and Karlovarske Mineralne Vody.

JANKOVIĆ POPOVIĆ MITIĆ

karanovic/partners

Integrites Advises LEO Payment System on Registration as International Payment System

Integrites advised Ukrainian payment system LEO on its registration as an international payment system.

LEO becomes the fourth "international" system of the 14 payment systems currently registered in Ukraine.

Noerr Advises on Merkur Sportwetten's Acquisition of Totolotek



Noerr advised Merkur Sportwetten, a member of the Gauselmann Group, on the acquisition of a majority stake in Totolotek, a member of the Intralot Group.

Merkur Sportwetten is a sports betting business with operations in Germany, Austria, Denmark, and Belgium. Totolotek has approximately 7.3% of the Polish betting market and over 250 distribution points.

Totolotek was advised by Dubois & Wspolnicy.

Cobalt Helps Wittix Obtain Electronic Money Institution License



Cobalt helped UAB Wittix obtain an electronic money institution license for unrestricted activity.

The license will enable Wittix to issue and/or acquire payment instruments and process incoming payments, execute payment transactions, and transfer funds on the payment account. In addition, Wittix will be entitled to make one-off direct debit transfers and execute payment transactions through a payment card or a similar device, as well as make money remittances, issue, distribute, and redeem electronic money.

Cobalt advised Wittix on all issues related to obtaining the license, drafted the license application documents, and represented the company before the Bank of Lithuania.

The Cobalt team was led by Senior Associate Justina Milasauskiene and Associate Justina Auzbikaviciene.

JULY 2019 ACROSS THE WIRE



Date covered	Firms Involved	Deal/Litigation	Value	Country
24-May	DSC Doralt Seist Csoklich; Schoenherr	Schoenherr advised South Korean investment fund KTB Investment & Securities and its subsidiary KTB Asset Management on the acquisition of 100% of Liegenschaftsbesitz GmbH from GENO Saturn Tower/T-Center Immobilien beteiligungs holding GmbH & Co.OG and BEGO-ZWP GmbH. The sellers were advised by DSC Doralt Seist Csoklich.	N/A	Austria
30-May	BPV Huegel	BPV Huegel advised Constantia Flexibles on a squeeze-out compensation settlement for minority shareholders of the formerly-listed Constantia Packaging AG.	EUR 50 million	Austria
3-Jun	Dorda; Noerr; Schmutzer & Ott- Sander	Dorda advised the Kapsch Group on the sale of CarrierCom and PublicTransportCom to S&T AG. Schmutzer & Ott-Sander Rechtsanwalte and the Munich office of Noerr advised S&T.	N/A	Austria
3-Jun	Cerha Hempel Spiegelfeld Hlawati	CerhaHempelSpiegelfeldHlawatiadvisedFrequent isAGonanIPOinFrankfurtandVienna.	N/A	Austria

Date covered	Firms Involved	Deal/Litigation Deal/Litigation	Value	Country
4-Jun	Binder Grosswang; Gibson, dunn & Crutcher; Kinstellar; Loyens & Loeff; Paul Hastings	Kinstellar, Gibson, Dunn & Crutcher, Stibbe, and Binder Groesswang advised CANAL+ Group, a subsidiary of the Vivendi group, on the acquisition of the M7 Group from Astorg, a European private equity firm. Paul Hastings and Loyens & Loeff advised Astorg and the other selling shareholders of the M7 Group.	N/A	Austria; Czech Republic; Hungary; Romania; Slovakia
4-Jun	Arnold Rechtsanwalte; Cerha Hempel Spiegelfeld Hlawati; Noerr; Wolf Theiss	Noerr and the Arnold law firm advised SignaRetail on the sale of Kika's Eastern European business to XXXLutz. XXXLutz was represented by CHSH on the purchase and by Wolf Theiss on the merger clearance process.	N/A	Austria; Czech Republic; Hungary; Romania; Slovakia
24-May	Baker McKenzie; Clifford Chance; Egorov Puginsky Afanasiev & Partners; Vlasova, Mikheel & Partners	Egorov Puginsky Afanasiev & Partners and Clifford Chance advised Citigroup Global Markets Limited and Raiffeisen Bank International AG as joint lead managers on the issuance and placement of Belarus's JSC Development Bank's corporate Eurobonds. Vlasova Mikhel & Partners advised JSC Development Bank on matters of Belarusian law and Baker McKenzie advised the bank on U.S. and English law.	USD 500 million	Belarus
28-May	Sorainen	Sorainen advised Sika on its acquisition of BellNECO, a company specializing in the production of polyurethane foams.	N/A	Belarus
11-Jun	Boyanov & Co.; Forlexa; Nestor Nestor Diculescu Kingston Petersen; Polenak Law Firm	Boyanov & Co., Polenak, and NNDKP advised Link Mobility Group AS Norway on the acquisition of Terracomm, a provider of B2C messaging services, from Allterco. Allterco was advised by Forlexa.	N/A	Bulgaria
13-Jun	CMS	CMS Sofia successfully represented CEZ in an administrative challenge to a regulatory decision by the Energy and Water Regulatory Commission on set prices for electricity sales in Bulgaria.	N/A	Bulgaria
14-Jun	CMS	CMS Sofia successfully convinced Bulgaria's Supreme Administrative Court to repeal a regulatory decision by the Bulgarian Energy and Water Regulatory Commission in favor of biomass producer Eco Energy Management Ltd.	N/A	Bulgaria
7-Jun	Divjak Topic Bahtijarevic; Kirkland & Ellis; Schoenherr	Schoenherr advised Tele2 AB on the EUR 220 million sale of its Croatian business, Tele2 Croatia, to the United Group. Kirkland & Ellis and Divjak, Topic & Bahtijarevic represented the BC Partners-backed United Group.		Croatia
23-May	Glatzova & Co.	Glatzova & Co. advised J&T Banka a.s. and J&T IB Capital Markets a.s. on preparation of a book-entry bonds issue for residential investment fund Natland.	CZK 300 million	Czech Republic
23-May	Kinstellar	Kinstellar advised Genesis Private Equity Fund II on the sale of its majority stake in KS Klima-Service to TROX GmbH, giving the German-based global producer of air handling equipment and filters 100% ownership of the company.	N/A	Czech Republic
27-May	JSK	JSK advised Prazska Energetika a.s. on its acquisition of Voltocm spol. s r.o.	N/A	Czech Republic
29-May	Dentons	Dentons Prague provided pro bono assistance to the Eduzmena Endowment Fund regarding its establishment and rules of operation.	N/A	Czech Republic
3-Jun	Kinstellar; Schoenherr	Schoenherr advised Portiva Private Equity a.s. on the acquisition of a 50% share in EAG SE, which, through its Carvagocom s.r.o. subsidiary, will operate an innovative platform to be used for buying, selling, and renting cars and other related services. Kinstellar advised EAG on the deal.	N/A	Czech Republic
4-Jun	Allen & Overy; CMS	Allen & Overy advised Alpiq AG on its sale of 100% of shares in Alpiq Generation to Sev.en Energy Group for EUR 280 million. CMS advised Sev.En Energy.	EUR 280 million	Czech Republic
4-Jun	White & Case	White & Case acted as transaction counsel on Rohlik.cz Finance's issue of CZK 777 million 6.6% guaranteed and secured notes due 2023, with the option to increase to CZK 1.166 billion.	CZK 777 million	Czech Republic
5-Jun	Clifford Chance	Clifford Chance advised J&T Real Estate CZ on the sale of the Rustonka office center in Prague's Karlin district to an investment trust fund established by Hana Alternative Asset Management and White Star Real Estate.	N/A	Czech Republic
5-Jun	Masek, Koci, Aujezdsky	Prague's Masek, Koci, Aujezdsky Law Firm advised Livesport Invest s.r.o. on its acquisition of Pragosport, a.s.	N/A	Czech Republic

Date covered	Firms Involved	Deal/Litigation Deal/Litigation	Value	Country
7-Jun	CMS; DLS Piper; Weil, Gotshal & Manges	CMS and DLA Piper advised Kiwi.com regarding General Atlantic's strategic investment in it. Weil, Gotshal & Manges acted as counsel for General Atlantic.	N/A	Czech Republic
11-Jun	Masek, Koci, Aujezdsky	Masek, Koci, Aujezdsky advised Livesport on its acquisition of Tapito, a tech start-up news application company, from O2 subsidiary Bolt Start Up Development.	N/A	Czech Republic
14-Jun	Kinstellar	$\label{thm:company} \textbf{Kinstellar helped Carvago, a Czech start-up in the used car sector, establish a company and set up its online platform.}$	N/A	Czech Republic
14-Jun	Glatzova & Co.; Kubica Zajic & Partners; Ondrej Kolar	Glatzova & Co advised the Pale Fire Capital investment group on its acquisition of 55 percent of shares in the Czech Aukro.cz business portal from Agora Development, Equity Partners, and Ladislav Chodak. The sellers were advised by Kubica Zajic & Partners. The remaining 45 percent of Aukro.cz is owned by Leverage Technology, advised by solopractitioner Ondrej Kolar.	N/A	Czech Republic
11-Jun	Clifford Chance; JPM Jankovic Popovic Mitic; Karanovic & Partners; Kocian Solc Balastik	JPM, Clifford Chance, and Kocian Solc Balastik advised Pepsico and Karlovarske Mineralne Vody on the acquisition of Knjaz Milos, a producer of mineral water and soft drinks in the countries of former Yugoslavia, from Mid Europa Partners. Karanovic & Partners advised the sellers.	N/A	Czech Republic; Serbia
30-May	Gutt Olk Feldhaus; Luther; PRK Partners; Schoenherr	PRK Partners advised the Remy Cointreau Group on the sale of its Czech and Slovak distribution companies to Germany's Mast-Jagermeister. Germany's Luther law firm provided advice on German elements of the deal, which closed in April 2019, while Germany's Gutt Olk Feldhaus and Schoenherr advised Mast-Jagermeister.	N/A	Czech Republic; Slovakia
17-May	Cobalt	$Cobalt\ advised\ Tallinna\ Linnatranspordi\ AS,\ a\ public\ transportation\ company\ owned\ by\ the\ City\ of\ Tallinn,\ on\ the\ addition\ of\ bus\ routes.$	N/A	Estonia
21-May	Cobalt	Cobalt analyzed the compliance of activities of AS Eesti Teed with the rules on state aid in Estonia. $ \\$	N/A	Estonia
21-May	Cobalt	Cobalt advised Estonia's Ministry of Economic Affairs and Communications on drafting a model energy performance contract for the public sector in compliance with the EU Energy Efficiency Directive.	N/A	Estonia
21-May	Cobalt	CobaltEstoniacompiledinstructionalmaterialsforKredExregardingthegeneralprinciplesofpublicprocurement.	N/A	Estonia
21-May	Leadell (Pilv)	Leadell successfully represented a former employee of Estonia's Labor Inspectorate in a dispute concerning the legality of release from service.	N/A	Estonia
27-May	Core Legal; Pohla & Hallmagi; PwC Legal	Pohla & Hallmagi successfully represented IDEMIA France SAS in a dispute with Gemalto in relation to the decision of the Estonian Police and Border Guard Board to award the contract for producing Estonian ID-cards to it. PwC Legal advised Gemalto and the Police and Border Guard Board was represented by Core Legal.	N/A	Estonia
29-May	Ellex (Raidla)	Ellex Raidla advised LHV Group AS regarding the public offering of additional subordinated bonds.	EUR 15 million	Estonia
29-May	Sorainen	Sorainen Estonia advised Artist Media on the sale of 90% of its shares to All Media Eesti, the parent company of Estonia's TV3's TV channel.	N/A	Estonia
30-May	Sorainen	Sorainen assisted Milrem AS obtain equity investments from multiple investors.	N/A	Estonia
3-Jun	Nove	Nove successfully represented firearms manufacturer Lewis Machine & Tool Company in a dispute regarding the public procurement of 5.56mm and 7.62mm automatic rifles for the Estonian Defense Forces.	EUR 75 million	Estonia
7-Jun	Fort	Fort advised LHV Pank on the acquisition of a Danske Bank unit consisting of a loan portfolio of Estonian private clients.	EUR 470 million	Estonia
7-Jun	Leadell (Pilv)	Leadell successfully represented construction company OU Monoliit and Monolit board member Jaak Reinmets in a criminal proceeding involving accusations of benefit fraud.	N/A	Estonia
11-Jun	Nove	Nove successfully represented Europark Estonia before the Estonian Supreme Court in a dispute involving whether the parking manager's leaving a contractual penalty notice under a client's windshield wiper constituted a reasonable way of delivery.	N/A	Estonia
3-Jun	Papapolitis & Papapolitis; Reed Smith	Reed Smith advised the EBRD on a EUR 55 million loan to Invel Real Estate to support its purchase of a 32.7% stake in Pangea from the National Bank of Greece. Papapolitis & Papapolitis advised Invel.		Greece

Date covered	Firms Involved	Deal/Litigation	Value	Country
17-May	Act Legal; Ban and Karika Attorneys at Law	Ban and Karika Attorneys at Law in cooperation with Act Legal advised the Share Now carsharing service on its entrance into Budapest.	N/A	Hungary
3-Jun	Kinstellar; Szecsenyi & Partners	Szecsenyi and Partners advised Wing Holding Zrt. on the purchase of the Liget Center office building in Budapest from the M7 Central European Real Estate Fund I, managed by M7 Real Estate. Kinstellar advised the seller on the deal.	N/A	Hungary
28-May	Ellex (Klavins)	Ellex Klavins advised alternative investment fund manager SIA SG Capital Partners AIFP on raising investments for the commercial real estate fund SG Capital Partners Fund I KS it manages.	EUR 80 million	Latvia
29-May	Cobalt; Sorainen	Cobalt Estonia advised venture capital firm Karma Ventures and Sorainen Latvia advised Practica Capital on their co-financing of EUR 5 million series A investment in Sonarworks.	EUR 5 million	Latvia
3-Jun	Ellex (Klavins); Sorainen	Ellex Klavins advised Baltic Horizon on its acquisition of 100% of Tampere Invest SIA, which owns the Galerija Centrs shopping center in Riga, from Linstow AS. Sorainen advised Linstow.	EUR 75 million	Latvia
4-Jun	Cobalt	Cobalt advised AB SEB Bankas on arranging the EUR 70 million notes issue program of AS Attistibas Finansu Institucija Altum and issuance of EUR 15 million notes with a yield of 0.95%.	EUR 70 million	Latvia
21-May	Cobalt	Cobalt Vilnius advised Interactio, a Lithuanian start-up that developed a smart interpretation system, on attracting an investment of EUR 435,000 from business angels and the Co-Investment Fund.		Lithuania
22-May	Cobalt; Motieka & Audzevicius	Motieka & Audzevicius advised Orion Private Equity Fund I on the acquisition of a stake in Lithuania's Alna Business Solutions, Alna Software, and DocLogix IT companies. Cobalt advised the seller, the Alna Group.	N/A	Lithuania
22-May	Sorainen	Sorainen advised Barclays Group Operations Lithuania on the transfer of the Rise Vilnius startup hub to Swedbank.	N/A	Lithuania
29-May	CEE Attorneys	CEE Attorneys successfully represented Audejas in a dispute against Vilniaus Miesto Projektai, which is managed by investment fund Lord LB Asset Management.	N/A	Lithuania
29-May	Fort	Fort represented 200 buyers of non-issued Snoras shares in their successful claim for procedural interest for the period of litigation against the Lithuanian state enterprise Deposit and Investment Insurance.	N/A	Lithuania
5-Jun	Glimstedt	Glimstedt advised Vastint Lithuania on an agreement with the Mitnija construction company in regard to the construction of a 55,000-square-meter office park in Vilnius.	N/A	Lithuania
5-Jun	Walless	Walless successfully defended the interests of Luminor Bank in the Court of Justice of the European Union.	N/A	Lithuania
12-Jun	Sorainen; TGS Baltic	TGS Baltic advised KuB Koinvesticinis Fondas and Sorainen advised Open Circle Capital on their joint investment of EUR 200,000, made with the Lithuanian network of business agents LitBAN, in artificial intelligence start-up Attention Insight.		Lithuania
12-Jun	Sorainen	$Sorainen\ helped\ Verse\ Payments\ Lithuania\ obtain\ an\ electronic\ money\ institution\ license.$	N/A	Lithuania
13-Jun	Sorainen	So rainen successfully represented Unis Steel Baltija before the Lithuanian Supreme Court.	N/A	Lithuania
13-Jun	TGS Baltic	TGS Baltic advised the Smart Energy Fund, powered by Lietuvos Energija, on its investment in Moixa, a UK-based company developing smart energy storage devices and virtual power plant technologies.	EUR 500,000	Lithuania
13-Jun	Glimstedt; Sorainen	Glimstedt advised AB Grigeo and UAB Grigeo Investiciju Valdymas on an investment and shareholders agreement regarding a EUR 30 million investment into the companies by UAB BSGF Salvus, a subsidiary of the INVL Baltic Sea Growth Fund.	EUR 30 million	Lithuania
14-Jun	Cobalt	Cobalt helped UAB Wittix obtain an electronic money institution license for unrestricted activity.	N/A	Lithuania
17-May	Dentons; Weil, Gotshal & Manges	Dentons Warsaw advised Kajima Student Housing Limited on the acquisition of a majority stake in Student Depo, the operator of a chain of student dormitories in Poland, from Oaktree Capital Management. Weil, Gotshal & Manges advised the seller on the deal, which left former JV partner Griffin Real Estate Partners retaining its 10% share in the chain.	N/A	Poland
17-May	Allen & Overy; Dentons; Hogan Lovells	Hogan Lovells advised Xcity Investment Sp. z o.o. and Dentons advised HB Reavis on their sale of the West Station office complex in Warsaw to Mapletree Investments. Allen & Overy advised Mapletree on the acquisition.	N/A	Poland
22-May	Hogan Lovells; Magnusson	The Warsaw office of Hogan Lovells advised the ISOC Group on the acquisition of three class A Business Garden Wroclaw I office buildings from Vastint Polska. Magnusson advised the seller on the deal.	N/A	Poland

Date covered	Firms Involved	Deal/Litigation	Value	Country
23-May	Zieba & Partners	Zieba & Partners advised Skanska Residential Development Poland on the acquisition of two real estate properties.	PLN 70 million	Poland
29-May	BSWW Act Legal	BSWW Act Legal in Poland advised Rank Progress S.A. on its sale of over eight hectares of investment land to Vantage Development S.A.	PLN 75 million	Poland
29-May	Allen & Overy; EY Law; Hogan Lovells	Hogan Lovells Poland advised the owner of Cinema 3D S.A. on the sale of its Polish portfolio N/ to Vue International. Allen & Overy advised Vue International and its Polish subsidiary Multikino on the acquisition. EY Law helped Vue International obtain the consent of The President of the Office of Competition and Consumer Protection for the transaction.		Poland
3-Jun	Dentons	Dentons advised a syndicate of six banks, including the EBRD, Bank Pekao S.A., and DNB Bank Polska S.A., on a EUR 290 million loan to Potegowo Mashav for the construction and operation of a wind farm in Northern Poland.	EUR 290 million	Poland
3-Jun	Greenberg Traurig	Greenberg Traurig Poland advised Cyfrowy Polsat on the issue of series B bonds.	PLN 1 billion	Poland
3-Jun	Act Legal	Act Legal Poland advised Heli Aviation Service Sp. z o.o. on the purchase of an AW169 helicopter manufactured by Leonardo S.p.A., formerly AgustaWestland.	N/A	Poland
4-Jun	Studnicki, Pleszka, Cwiakalski, Gorski	SPCG Studnicki, Pleszka, Cwiakalski, Gorski successfully represented Engie Zielona Energia Sp. z o.o. in a dispute involving its lease of land for a wind farm and attempt to reduce the lease due to the collapse of the renewable energy market and the dramatic fall in electricity prices and green certificates.	N/A	Poland
5-Jun	Greenberg Traurig; Shearman & Sterling	Greenberg Traurig and Shearman & Sterling advised Societe Generale on the PLN 1.83 billion sale of Euro Bank, its retail banking subsidiary in Poland, to Bank Millennium.	PLN 1.83 billion	Poland
5-Jun	Aplaw Artur Piechocki	APlaw advised ComCERT S.A. on the sale of its shares to IT software developer Asseco Poland S.A.	N/A	Poland
11-Jun	Crido Legal; Dentons	Dentons advised Jozef Grzymala, a co-founder of Polish pharmaceutical company LEK-AM, on the sale of the company to the other co-founder, Andrzej Wyrzykowski. Crido advised Andrzej Wyrzykowski.	N/A	Poland
11-Jun	Dentons; Linklaters	Dentons Real advised GLL Real Estate Partners on a sale of shares in the company owning the Renaissance office building in central Warsaw to KanAm Grund Group. Linklaters advised the buyers on the deal.	N/A	Poland
14-Jun	Studnicki, Pleszka, Cwiakalski, Gorski	SPCG Studnicki, Pleszka, Cwiakalski, Gorski successfully represented Air Liquide Global E&C Solutions Poland S.A. in Poland's Supreme Administrative Court regarding corporate income tax.	N/A	Poland
14-Jun	Dubois & Wspolnicy; Noerr	Noerr advised Merkur Sportwetten, a member of the Gauselmann Group, on the acquisition of a majority stake in Totolotek, a member of the Intralot Group. Totolotek was advised by Dubois & Wspolnicy.	N/A	Poland
24-May	CEE Attorneys	CEE Attorneys in Romania advised EshopWedrop Group, the B2C service of Xpediator Plc., on signing a franchise agreement with TMM Express in Poland.	N/A	Poland; Romania
24-May	Biris Goran; Nestor Nestor Diculescu Kingston Petersen	Biris Goran advised Global Vision on its agreement with Globalworth to develop a EUR 35.5 million logistic project in the southeastern Romanian town of Chitila. Nestor Nestor Diculescu Kingston Petersen advised Globalworth on the deal.		Romania
27-May	Appelby; Clifford Chance	Clifford Chance Badea advised NE Property B.V. on the implementation of a EUR 1.5 billion Medium Term Program guaranteed by NEPI Rockcastle plc, as well on the launch of a 2.625% EUR 500 million bonds issue due 2023 under the program. Appleby assisted Clifford Chance in advising NEPI Rockcastle.	EUR 1.5 billion	Romania
31-May	Enache Pirtea and Associates; PCA Lawyers	PCA Lawyers advised Badea Medical SRL on the sale of a 65% stake in Badea Medica Center of Excellence to MedLife. Enache Pirtea and Associates advised MedLife on the acquisition.	N/A	Romania
31-May	Dragne & Asociatii	Dragne & Asociatii successfully represented the Jewish Community of Galati in a 55-year dispute that involving property that was taken over by the Communist regime, and which necessitated overturning a decision that had been rendered in 1964.	N/A	Romania
5-Jun	Dentons; Kinstellar	Dentons advised CEE Equity Partners on an agreement with the Brise Group for the investment, modernization, and development of the first open access agriculture infrastructure platform, based on 15-grain silos and logistic hubs in Romania. Kinstellar advised Brise on the deal.	EUR 60 million	Romania

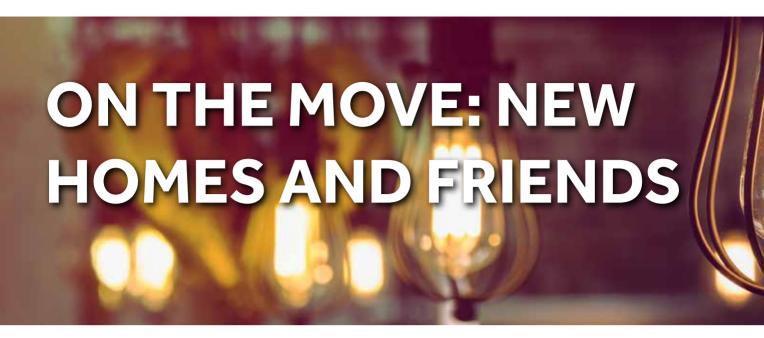
ACROSS THE WIRE JULY 2019

Date covered	Firms Involved	Deal/Litigation	Value	Country
5-Jun	Eversheds Sutherland; MPR Partners Maravela, Popescu & Roman; Wolf Theiss	Maravela, Popescu & Roman advised wiper blade manufacturer Trico on the acquisition of Nathewiper systems business of Federal-Mogul Motorparts. Wolf Theiss advised Federal-Mogul on matters of Romanian law, acting with lead counsel Eversheds Sutherland.		Romania
13-Jun	Tuca Zbarcea & Asociatii	Tuca Zbarcea $\&$ Asociatii successfully represented Federatia Romana de Fotbal against Football Club U Craiova S.A.	EUR 300 million	Romania
14-Jun	Clifford Chance; Popovici Nitu Stoica & Asociatii	Popovice Nitu Stoica & Asociatii advised Italy's CLN-Coils Lamiere Nastri – the owner of Romania's MW Romania SA Dragasani car factory – on a EUR 134 million financing received from the IFC and Cassa Depositi E Prestiti SPA. The lenders were advised by Clifford Chance Badea.	EUR 134 million	Romania
14-Jun	Popovici Nitu Stoica & Asociatii	Popovici Nitu Stoica & Asociatii advised Dedeman on its acquisition of The Bridge 2 office complex in Bucharest from developer Forte Partners.	N/A	Romania
17-May	Latham & Watkins	Latham & Watkins advised HeadHunter Group PLC, an online recruitment platform operating in Russia and the Commonwealth of Independent States, on the initial public offering of its American Depositary Shares.	USD 253 million	Russia
23-May	Nektorov Saveliev & Partners	Nektorov Saveliev $\&$ Partners was assigned the bondholder representative for the issuance of three million non-convertible interest-bearing certificated exchange-traded bonds of PAO AKB Avangard.	RUB 3 billion	Russia
11-Jun	Akin Gump; Cleary Gottlieb Steen & Hamilton; Debevoise; Linklaters	Akin Gump advised Russian Internet and IT company Mail.ru on the formation of a joint venture with the Alibaba Group, a global digital commerce company, PJSC MegaFon, a pan-Russian operator of digital opportunities, and the Russian Direct Investment Fund, Russia's sovereign wealth fund. Cleary advised MegaFon on the deal, while Linklaters advised the Russian Direct Investment Fund. Debevoise advised Alibaba.	N/A	Russia
17-May	Kolcuoglu Demirkan Kocakli; Paksoy	Paksoy advised the Ergo insurance company on the sale of Ergo Sigorta, the company's non-life insurance subsidiary, to HDI Sigorta. Kolcuoglu Demirkan Kocakli advised HDI on the deal.	N/A	Turkey
17-May	Akugur Law Firm; Gide Loyrette Nouel; O'Melveny & Myers	Gide and O'Melveny & Myers advised Electronics For Imaging Inc., a Silicon Valley-based digital imaging company, on the acquisition of BDR Boya Kimya Sanayi ve Ticaret Anonim Sirketi. The Akugur Law Firm advised BDR Boya Kimya.	N/A	Turkey
21-May	Baker McKenzie; Unsal Avuktalik Ortakligi	Baker McKenzie advised BNP Paribas on matters of English and Turkish law related to its EUR 50 million sustainability-linked loan to Turkcell. Unsal Avukatlik Ortakligi advised Turkcell.		Turkey
27-May	Baseak	Baseak advised Taxim Capital on Besifarma Ilac A.S. on an undefined investment in Alke Saglik Urunleri Sanayi ve Ticaret A.S.	N/A	Turkey
22-May	Sayenko Kharenko	Sayenko Kharenko advised Deutsche Bank on a EUR 529 million facility extended to Ukraine under a World Bank guarantee.	EUR 529 million	Ukraine
27-May	Avellum; Sayenko Kharenko	Avellum advised Dobrobut and its shareholders on the sale of a minority stake in the company to Horizon Capital. Sayenko Kharenko advised Dobrobut on the deal.	N/A	Ukraine
5-Jun	Aequo	Aequo represented the Dragon Capital Group before the Antimonopoly Committee of Ukraine in relation to obtaining merger clearance for its May 2019 sale of Chumak to Delta Wilmar.	N/A	Ukraine
11-Jun	Ilyashev & Partners	Ilyashev & Partners represented Ukranian state-owned enterprise Antonov before the District Court of Kyiv in proceedings against Rosaviation and AMTES GmbH.	N/A	Ukraine
12-Jun	Integrites	Integrites advised Ukrainian payment system LEO on its registration as an international payment system.	N/A	Ukraine
13-Jun	Sayenko Kharenko	Sayenko Kharenko advised the Bergner group on the acquisition of a majority interest in an unidentified Ukrainian distribution company, and on the establishment of a joint venture with an unidentified local partner aimed at developing the distribution network for Bergner products in Ukraine.	N/A	Ukraine
13-Jun	Asters	Asters successfully represented Sanofi Ukraine in a challenge to the Antimonopoly Committee of Ukraine's finding of a competition law violation.	N/A	Ukraine

 $Full\ information\ available\ at: www.ceelegal matters.com$

Period Covered: May 15, 2019 - June 14, 2019

JULY 2019 ACROSS THE WIRE



Lazareff Le Bars Opens Knowledge Support Service Hub in Hungary



France's Lazareff Le Bars has opened a Budapest office to serve as a hub to provide knowledge support services to the firm's lawyers.

Lazareff Le Bars was established in Paris in 2009 by Serge Lazareff and Benoit Le Bars as a boutique specializing in international dispute resolution, arbitration, and complex litigation.

Serge Lazareff served as an interpreter and aide to General Eisenhower during the drafting of the Washington Treaty establishing NATO, subsequently became a renowned international arbitrator who was involved in more than 200 institutional or *ad hoc* arbitration proceedings, and ultimately became the second President of the ICC Institute of World Business Law. He died in 2012.

Benoit Le Bars is the current Managing Partner of the firm. He has experience in arbitration forums around the world, and he has earned particular recognition for his expertise with arbitration in Africa. He describes his firm as "notably active in investor-state arbitration, often involving major investments and infrastructure projects."

In a conversation with CEE Legal Matters, Le Bars explained that he is in the process of creating a full-time team in Budapest, and that the office is part of Lazareff Le Bars' program of expansion, which — in addition to Budapest — includes Brussels and will soon include offices in Senegal and the United Arab Emirates. "Reorganizing in such fashion positions us to best handle the size, scale and complexities of a modern law firm. Having offices in these places ensures a close relationship with our clients, which is crucial in our work," he says.

Budapest was selected as a suitable location for the establishment of a shared service hub to provide the firm with knowledge support services to lawyers such as research and analytics, legal and financial document services, and legal and discovery services, all of which, Benoit reports, are designed to improve efficiency and delivery to clients. "Our clients exist in a challenging commercial environment and appreciate when their lawyers are as focused and cost efficient as they are," he said. The office will also house certain back office functions such as marketing and finance. Le Bars explained that, in choosing Budapest for the firm's office in CEE, he focused on the diversity of talent available, including the quality of education and the availability of language skills that can be found in the Hungarian capital. He conceded the choice was also influenced by his affection for the city.

By Mayya Kelova

ON THE MOVE JULY 2019



NNDKP Team Spins-Off to Launch Simion & Baciu



Cosmina Simion, Ana-Maria Baciu, Andreea Bende, and three other lawyers have left Romania's Nestor Nestor Diculescu Kingston Petersen to set up Simion & Baciu.

Baciu, who had been with NNDKP since 2003, headed the firm's IP department and Pharma and Health Care practice group and co-headed the Gaming and Consumer Protection practice groups.

Simion, who co-headed NNDKP's Gaming and Consumer Protection practice groups, joined the firm in 2015 after spending five years as a Counsel with DLA Piper and another nine as a Counsel with Central European Media Enterprises. Earlier still, she spent two years as an Associate with Taylor Wessing.

Bende started her career at NNDKP in 2005 and was appointed Partner in January 2019.

The three are joined by Senior Associates Andrei Cosma and Ana Maria Coruga, Associate Teodora Popescu, and Office Manager Simona Naie.

According to a Simion & Baciu press release, the new firm will cover various practice areas, including intellectual property, gaming and gambling, life sciences, consumer protection and advertising, technology and data protection. According to that press release: "We like to describe ourselves as more than lawyers and consultants, but first of all, as happy people that like what they do, that are good at trying and finding solutions and are naturally focused on their clients' needs and expectations. We like to build long-term relations with all our clients and aim to add our resources and knowledge to those of our clients and to integrate our assistance to the experience of the entities for which we work."

An NNDKP statement announced that "NNDKP, Ana-Maria Baciu, and Cosmina Simion intend to maintain their collaboration with respect to certain areas of practice to ensure that clients have access to the most appropriate legal service in projects requiring such complementarity."

By Radu Cotarcea

Schoenherr to Open Office in Linz



Schoenherr has announced that it will open a new office in Linz this autumn.

Arabella Eichinger, who comes from Upper Austria and was appointed Partner at Schoenherr in February of this year, will manage the new office and will be joined with seven other lawyers.

Schoenherr Managing Partner Michael Lagler commented: "Upper Austria is a growing economic area with a strong university uniting innovation, industry, and technology. We will be closer to our Upper Austrian clients and look forward to an even stronger cooperation."

"Upper Austria has been on our radar for quite some time now," Eichinger said. "It's a logical response to our steadily-growing client base there. With leading experts in Austria and our strong CEE/SEE network, we can now offer a significant added value locally."

By Mayya Kelova

JULY 2019 ACROSS THE WIRE

Kinstellar Launches Asset Solutions Practice



Kinstellar has announced the launch of a dedicated Asset Solutions practice, led by Bratislava-based Partner Denise Hamer, who describes it as "a multi-discipline/multi-jurisdiction practice sector focused on non-performing and non-core assets."

According to Hamer, "the C/SEE market has moved since the huge NPL portfolio heyday to a more private equity approach. Increasingly, sellers are selling [and] investors are buying smaller portfolios and single name assets and instead of just 'dialing for dollars,' investors are actually working the assets. Accordingly, Asset Solutions offers the entire spectrum of legal support in a one-stop shopping platform."

By David Stuckey

Voinescu Lawyers Enters into Alliance with LexQuire



Voinescu Lawyers in Romania has entered into an alliance with Lexquire Tax & Law, which has offices in the Netherlands, Germany, Belgium, France.

According to Lexquire, "our natural cross-border vision was behind the consolidation of our identity as an international team of highly qualified professionals providing legal and tax advice in multiple jurisdictions to a wide variety of clients, from SMEs to multinational companies active in various sectors."

By David Stuckey

PARTNER APPOINTMENTS

Date Covered	Name	Practice(s)	Firm	Country
27-May	Tomas Bairasauskas	Insolvency/Restructuring	WINT	Lithuania
27-May	Marius Matiukas	Banking/Finance	WINT	Lithuania
21-May	Bogdan Bunrau	Corporate/M&A	Bondoc si Asociatii	Romania
21-May	Diana Ispas	Banking/Finance; Capital Markets	Bondoc si Asociatii	Romania
21-May	Raluca Voinescu	Competition; Life Sciences	Bondoc si Asociatii	Romania
3-Jun	Krisztina Voicu	TMT/IP; Life Sciences	CEE Attorneys	Romania
13-Jun	Alina Stavaru	Corporate/M&A Private Equity	Allen & Overy	Romania
16-May	Alla Kozachenko	Corporate/M&A	DLA Piper	Ukraine
12-Jun	Bohdan Masekha	Litigation/Disputes; Corporate/M&A	LEZO Attorneys at Law	Ukraine
12-Jun	Serhii Mazur	TMT/IP; Corporate/M&A	LEZO Attorneys at Law	Ukraine
12-Jun	Andriy Agafonov	Banking/Finance; Litigation/ Disputes	LEZO Attorneys at Law	Ukraine

*Erratum: CMS Sofia Managing Partner Kostadin Sirleshtov was accidentally included in the "Partner Appointments" table of the June 2019 issue of the CEE Legal Matters magazine. In fact, Sirleshtov was appointed Managing Partner of CMS's Sofia office in May 2019 – he has been a partner at CMS since 2007. We apologize for the error.

ON THE MOVE JULY 2019

PARTNER MOVES

Date Covered	Name	Practice(s)	Firm	Moving From	Country
24-May	Michael Horak	TMT/IP	Binder Groesswang	Salomonowitz Horak	Austria
3-Jun	Andrei Vashkevich	Litigation/Disputes; Real Estate	Lex Torre	Stepanovski, Papkul & Partners	Belarus
22-May	Arkadiusz Ruminski	Corporate/M&A	SSW Pragmatic Solutions	Noerr	Poland
7-Jun	Agnieszka Fedor	Labor	Soltysinski Kawecki & Szlezak	Dentons	Poland
3-Jun	Cosmina Simion	TMT/IP; Life Sciences	Simion & Baciu	Nestor Nestor Diculescu Kingston Petersen	Romania
3-Jun	Ana-Maria Baciu	Compliance; Gambling	Simion & Baciu	Nestor Nestor Diculescu Kingston Petersen	Romania
3-Jun	Andreea Bende	TMT/IP; Compliance	Simion & Baciu	Nestor Nestor Diculescu Kingston Petersen	Romania
6-Jun	Ihor Olekhov	Banking/Finance	CMS	Baker McKenzie	Ukraine

IN-HOUSE MOVES AND APPOINTMENTS

Date Covered	Name	Company/Firm	Moving From	Country
22-May	Eva Kohoutova	GSK (Legal Manager for CEE)	Havel & Partners	Czech Republic
28-May	Eniko Uveges	Deloitte (Head of In-House Legal)	Cargill (Lead Lawyer)	Hungary
7-Jun	Joanna Blaszczyk	Polish Development Fund (Head of Legal)	Polish Development Fund (promoted internally)	Poland
6-Jun	Andreea Lisievici	Volvo Cars (Head of Data Protection Compliance)	PrivacyOne	Sweden
21-May	Ceren Kartari	Facebook (Associate General Counsel)	British American Tobacco (Head of Legal, Turkey and North Africa Area)	United Kingdom
20-Feb	Ilya Kudryashov	VK Partners	Silvercliff Capital	Russia

OTHER APPOINTMENTS

Date Covered	Name	Company/Firm	Appointed To	Country
5-Jun	Arabella Eichinger	Schoenherr	Head of Linz Office	Austria
3-Jun	Alexadner Lobaty	Stepanovski, Papkul & Partners	Head of Litigation Practice	Belarus
3-Jun	Dmitry Kovalchik	Stepanovski, Papkul & Partners	Head of Real Estate Practice	Belarus
21-May	Marius Liatukas	Magnusson	Managing Partner for Lithuania	Lithuania
14-Jun	Denise Hamer	Kinstellar	Head of Asset Solutions Practice	Slovakia

Full information available at: www.ceelegalmatters.com

Period Covered: May 15, 2019 - June 14, 2019

JULY 2019 LEGAL MATTERS



HUNGARY: MAY 29



"We are living in historic times," says Janos Toth, Wolf Theiss Partner in Hungary. "Not only our legal system is transforming, but also a whole new approach to business is evolving."

Toth singles out the proposed draft of a new Insolvency and Bankruptcy Law in Hungary as among the most significant changes. According to him, the new law is long-awaited, as the previous Law on Insolvency and Bankruptcy was introduced nearly 30 years ago. Although that previous law was amended several times, Toth says that it "no longer served the recent legal trends or reflected how business in Hungary has changed since the early 90s." According to him, it caused many problems, especially when "prominent businesses with huge customer bases run into trouble, creating loud social turbulence."

"Obviously, those were the signs to lawmakers that something

should be done differently," Toth says, noting that the government already reformed other substantial cornerstones of the country's business laws, such as the Hungarian Civil Code and Civil Procedural Law. "It was really high time to do something on the bankruptcy front," he says.

According to Toth, the new law will be combined with further changes to a law on corporate registration and should be introduced soon so that the parliament is able to vote on it this fall. At the moment the draft law is expected to go through public consultations and discussion with various stakeholders. Toth says that the expectation is that the process will result in "legislation following the most eminent trends in Western Europe and the US." Ultimately, he hopes to see increased legal predictability and business security, expedited and efficient processes, and a decreased burden on creditors.

Once passed, the law is scheduled to come into force in mid-2020, he says, "which gives the current government ample time to fine-tune the law if necessary and see how it works."

In the meantime, Hungary is "delicately balancing" between the various geopolitical powers, trying to keep a positive relationship with each of the important global actors, says Toth. Indeed, within the past month Hungarian Prime Minister Viktor Orban has met with both US President Donald Trump and Premier of the Republic of China Li Keqiang. "The primary interest of our government is to maintain excellent relationship with each of those mammoths, as well as Russia," he says, adding that these relationships help to attract new investments, and pointing to the Russian-built Paks 2 Nuclear Power Plant and the Budapest-Belgrade railway that will be financed by the Chinese government.

THE BUZZ JULY 2019

How the economic clashes between the US and China and Europe will evolve is unknown, says Toth, noting that the outcome of the continent-wide EU parliamentary elections held on May 26, 2019, would certainly play a role in that process. "No one can really predict how it will play out in terms of business outlook," he says, suggesting that keeping the "European economies abreast with the rest of the world would be at stake."

By Mayya Kelova

BOSNIA & HERZEGOVINA: JUNE 4



"Things are pretty quiet, and there aren't any big developments," begins Sead Miljkovic of Miljkovic & Partners, when asked for the Buzz in Bosnia & Herzegovina. He reports that "infrastructural projects and consolidations in the bank sector" are active at the moment, as well as "financing of public projects," but he adds that "none of it is large-scale."

Miljkovic points out that the biggest hurdle to any "exciting developments" is the fact that the BiH Government remains incomplete following last October's elections. "Neither the Federal nor the State nor Local Governmental institutions are fully formed and functioning," Miljkovic says. "This slows business down, and puts a halt on NATO integration as well as any perceivable EU accession movements." According to him, "the political picture is quite complex and is a major obstacle to realizing any previously-started projects or beginning work on any new ones," and he reports that "the last time something big in terms of legislation passed was at the end of 2017/start of 2018," and that nothing of major importance has happened since.

Asked about the state of the BiH legal market, Miljkovic says that no new firms have entered in the previous year, nor are there any exits likely to impact the current market composition. "Everything is pretty stable and has not changed much in the past year, and it seems that this trend will continue for the immediate future."

By Andrija Djonovic

CROATIA: JUNE 11



Divjak, Topic Bahtijarevic Partner Mario Krka says that "there are currently three major legislative changes that everybody in Croatia is talking about: changes to the Corporate Law Act, certain tax bylaws amendments, and upcoming changes to the Civil Procedure Act."

"Corporate law changes are what lawyers are talking about most," Krka says. The most significant of those changes, he says, involve e-incorporation of companies, part of a broader strategy designed to improve access to courts and generally clear things up from a legal perspective.

Tax changes are also an "especially hot topic," Krka says, referring to changes that will allow Croatia's Tax Authority to block Internet pages if it "believes that these pages enable people to buy goods and services in a way that circumnavigates the current regulatory framework." The Tax Authority will accomplish that by "requesting a blockage from the network regulator, which will, in turn, apply pressure on Internet providers to shut these pages down."

Recently-proposed changes to the Civil Procedure Act, Krka reports, "will mostly serve to streamline practice and ease the current caseload the Supreme Court has on its plate." Croatia's Civil Procedure Act hasn't been amended in six years, he says, and he notes that the current "set of suggestions will lighten the court's workload, but will also deny citizens certain types of legal remedies."

Krka says that "the real estate sector is the most active right now" and that there is a significant "increase in the prices of properties both in the commercial and residential sectors, especially on the seaside and in Zagreb." He adds that there are some talks of a "major infrastructural project that will aim to revamp a portion of Zagreb next to the Sava river," but says that the contractors rumored to be working on the project are "the people that are linked to a similar project in Belgrade — The Belgrade Waterfront - which has a cloud of controversy around it."

Finally, Krka says that the recent European Parliamentary

JULY 2019 LEGAL MATTERS

elections led to a slight "shift towards the right." He concludes by saying that "the important question is the stability of the ruling coalition In Croatia," and he notes that any internal party turmoil may "have external impact, especially in terms of parties positioning for the Croatian parliamentary elections."

By Andrija Djonovic

BELARUS: JUNE 12



"Belarusian markets are abuzz with two things right now," explains Arzinger & Partner's Klim Stashevsky." The new strategy for attracting FDI and the M10 highway reconstruction project."

According to Stashevsky, the Belarusian Ministry of the Economy and the Agency for Investments and Privatization has prepared a *de facto* "road map" for FDI for main sector investments, which provides guidelines for all levels of government. According to Stashevsky, "the legal community was working on and it had a lot of involvement from foreign advisors." According to him, "the strategy is ready, we're only waiting for it to be adopted by the Government."

Stashevsky reports that "the government is launching a big project to reconstruct the M10 highway," and he says that the Ministry of Transportation and the EBRD are currently conducting a prequalification process to select a private partner. This is the first project that will be completed under Belarus's new Public-Private Partnership Act, he says, and thus it will "serve as a litmus test for projects for the next five years."

"As far as the political climate, everything is pretty stable," continues Stashevsky. "Next year will see Presidential elections, which have motivated the Government to make sure things are running smoothly." He says that President Alexander Lukashenko's announcement of plans to reform the country's Constitution, aiming to extend the powers of executive and legislative branches, was "met with a moderate response" and that "everybody sees it as an important change."

Finally, Stashevsky states that "the IT sector is booming in Belarus," and that the "forestry and woodworking industry sec-

tors are quite active" as well. He says that the "woodworking industry sector" is thriving due to it being a "source of energy for the market, which is preparing for the opening of the first nuclear power plant in Belarus, by the end of 2019 or start of 2020." He concludes by saying that real estate is seeing "a lot of action too, with companies from Poland, Russia, and China all working in Belarus on a significant number of projects."

By Andrija Djonovic

SLOVENIA: JUNE 13



"It has been busy in the business arena," says Marko Ketler, Senior Partner and Attorney at Law in cooperation with Karanovic & Partners, citing ongoing consolidation in the banking sector with the potential sale of Abanka, the third largest bank in Slovenia, and recent major M&A transactions, including the sale of Intereuropa, the largest Slovenian logistics company, to Posta Slovenije. "We can expect a busy summer with several large M&A deals pending."

Dispute resolution is another busy area, with the continued filing of lawsuits against banks by consumers who took loans denominated in CHF a few years ago, Ketler says.

There are two major legislative changes being considered, Ketler reports. The first is a new Companies Act, which is currently in its first reading and which is expected to be introduced in the next few months. Among the most significant changes contained in the law, Ketler says, is the requirement that all owners of shares in joint stock companies disclose their identity, which "might potentially force some owners to sell their shares." The law will also impose further limits on the establishment of companies in Slovenia.

The second changes Ketler cites are related to the introduction of a new Attorney Act. In the past few weeks, a first draft of the act was circulated among lawyers across the country for recommendations and feedback. The law was prepared by the Slovenian Bar Association and the Faculties of Law in Ljubljana and Maribor.

On a political front, Slovenia seems to be passive, says Ketler,

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who describes a general indifference in the country towards the EU parliamentary elections. "Slovenia has only eight seats and the people in general are not enthusiastic to vote," he says. In fact, the turnout for the EU parliamentary elections in Slovenia on May 24, 2019, was only 28% across the country, preserving the eight seats.

By Mayya Kelova

CZECH REPUBLIC: JUNE 20



"The main thing right now is the upcoming amendment to Act on Corporations," starts Kinstellar Partner Tomas Cihula, describing the situation in the Czech Republic. "The Parliament is considering proposals which seek to clarify some parts of the current legislative framework and that aim to ease the regulatory burden companies are facing." Cihula said that this overhaul was met with "approval from the business sector."

"Autonomous vehicles are a bit more of a cool topic, though," Cihula says, smiling. "The Czech Republic has a very strong automotive industry and driverless cars are a crucial step forward. There is a proposal for an act to regulate autonomous vehicles and infrastructural plans to accommodate them on the roads, and there is political pressure to pass this piece of legislation by next year so these cars can hit the road as soon as possible."

Another potential legislative change involves medical cannabis, Cihula says. The Czech Republic has legalized cannabis for medical purposes and there are "considerations to have the public health insurance reimburse 90% of its cost for the patients that use it." He adds that "there are a lot of companies active in this area that are looking forward to this happening."

Finally, Cihula says, "it's worth mentioning the new proposal for introducing collective actions." The main purpose of this newly-proposed legislation is to improve the position of consumers making claims against large corporations by pooling these claims and sharing costs of the procedure. This would also potentially provide a good source of revenue for the lawyers, he says, adding that "it is likely that the currently proposed legislation in the Czech Republic is inspired by the one in the US which is more claimant-friendly than the regime proposed by the EU." The proposed legislation aims to introduce "very broad discovery rules which would allow claimants to have extensive access to documents and data." It also seeks to enable both opt-in as well as opt-out regimes. "It is to be expected that large corporations will try and fight these changes, seeing as how it would potentially put them in a not-so-favorable position, so we can expect that the proposed draft will undergo some changes before it is passed by the Parliament."

By Andrija Djonovic

DID WE MISS SOMETHING?

We're not perfect; we admit it. If something slipped past us, and if your firm has a deal, hire, promotion, or other piece of news you think we should cover, let us know. Write to us at: press@ceelm.com



JULY 2019 LEGAL MATTERS





It has been over a year since the European Union's General Data Protection Regulation became mandatory across Europe, marking a seismic shift in the way that companies collect, process, and handle personal data. Countries across the European Union and beyond have adapted their national laws to meet the requirements of the GDPR - with many introducing local derogations as permitted by the GDPR.

Despite some early apocalyptic predictions about the impact of the GDPR, the reality has been far less dramatic. Nevertheless, it has been a serious consideration for businesses to take on board – bringing about a diverse range of challenges and lessons.

Data Breaches

The protection of personal data and privacy is the cornerstone of the GDPR. According to the International Association of Privacy Professionals (IAPP), more than 89,000 data breaches have been reported to the various EEA regulators in the last year. As the data below shows, countries across CEE have not been immune.

Bulgaria

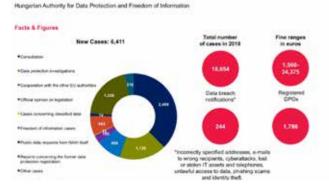




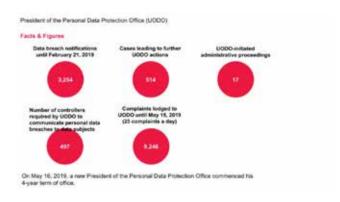
Czech Republic



Hungary



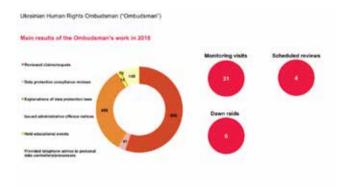
Poland



Romania



Ukraine



Impact of Enforcement Powers

So far, according to the European Data Protection Board Report, European regulators have used their enforcement powers to levy fines totalling over EUR 56 million against 91 companies (including EUR 50 million against a single organization). Although this figure may seem significant, with the exception of the EUR 50 million penalty, the fines have been fairly conservative and nowhere near the maximum the regulators are able to order.

Despite this, the numerous enforcement activities carried out by supervisory authorities across CEE show that businesses will be reprimanded should they fail to comply with personal data protection obligations. This often means hefty fines - which can reach up to 4% of an organization's annual turno-

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Bulgaria



Estonia



Latvia



Poland



Russia

karanovic/partners

Slovenia



ATTORNEYS AT LAW

Czech Republic

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ESTONIA LATVIA LITHUANIA BELARUS

Lithuania

MARAVELA | ASOCIAŢII

Romania

karanovic/partners

Serbia



Ukraine



ver - and significant reputational damage.

In Poland, the Personal Data Protection Office fined a company a staggering EUR 220,000 for failing to fulfil its information obligations. The company in question ran a commercial database composed of over 7.5 million records of personal data collected from public registers. While it posted information about processing personal data on its web-

site and sent privacy notices to those persons whose e-mail addresses it had in its database, the company did not send privacy notices to the remaining persons using their postal addresses or telephone numbers, which, it argued, given the significant cost of sending traditional letters or sending text messages, would involve disproportionate effort. The Polish authority did not agree with this argument, stating that: (i) posting the privacy policy on the company's website is not sufficient from a GDPR perspective, and (ii) "high costs" related to a particular operation cannot be deemed a "disproportionate effort" that justifies failing to fulfil the company's information obligation.

In another breach, a company in Bulgaria was fined EUR 27,098 for the unlawful use of personal data. A customer allegedly requested to switch from a subscription to a pre-paid service at a telecommunications company. However, it was not the customer who signed the request form – the signature was falsified. As a result, the company processed the underlying personal data for a purpose to which the customer had not consented.

These cases highlight the importance of "consent" – arguably one of the most misinterpreted aspects of GDPR. Under the regulations, unless other available legal grounds for processing personal data can be met, companies must ensure that the data subject has consented to processing his or her personal data, and that a thorough record of how and when an individual gives consent is stored. It is crucial that businesses undertake a careful analysis of the available legal bases for processing and keep up to date with local regulatory guidance, as rules vary from country to country. For example, in Romania political parties, NGOs, and national minority organizations can process personal data without the express consent of the data subject. And shortly before this article was published,

the Hungarian National Authority for Data Protection and Freedom of Information levied its highest ever data protection fine – EUR 100,000 – against the annual "Sziget" music and arts festival upon the discovery that the organizers of the event were asking for the consent of guests to security screening (including photocopying personal IDs and taking photos at the entry gate), without proving their legitimate interest in the data processing.

Cybersecurity: The Constant Threat

Cybersecurity remains a real threat to individuals and businesses across CEE, and cyber-attacks impose enormous costs on their victims.

Underlining the need for robust breach management procedures, data security requirements, and encryption technology, an organization in Hungary was fined EUR 34,375 following a large-scale cyberattack. In this case, the hacker disclosed information on the vulnerability of the organization's system - including the command used for the attack. The disclosure of the identification data of more than 6,000 users (including names, email addresses, usernames, and passwords) posed a high risk and the company was subsequently penalized. Meanwhile, in the Czech Republic, e-commerce company Internet Mall, a.s. was fined EUR 58,800 by the authorities for failing to secure and prevent a large leak of customer personal data onto the public cloud service Ulozto.cz.

When it comes to processing employee data, it is vital that businesses adhere to the legal requirements governing data privacy. This warning follows a company's EUR 1,278 fine by the Bulgarian authorities for carrying out background checks on the employment and insurance status of an ex-employee without a legitimate basis.

Conclusion

Information, both personal and commercial, is usually delicate and often powerful. The GDPR was introduced to harmonize data privacy laws across Europe and give greater protection and rights to individuals. Companies across CEE have rapidly become familiar with the rigor with which the GDPR's requirements are imposed. In addition to a thorough awareness of the GDPR it is crucial that businesses in the region stay abreast of local regulator guidance, and that they develop a robust compliance culture. Failure to take these essential measures may result in harsh and costly consequences.

Dora Petranyi, CEE Managing Director, CMS Cameron McKenna Nabarro Olswang and Johannes Juranek, Managing Partner, CMS Reich-Rohrwig Hainz

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MARKETING LAW FIRM MARKETING: NOT ENOUGH TIME

This time, our law firm marketing friends across CEE considered the following question:

"What one part of your job would you most appreciate having more help with — not in terms of training or capability, but simply in terms of time?"



be doing.

Formatting. Working with lawyers and particularly litigators can often make your life miserable as they spot formatting mistakes from across the room. For a creative marketeer focusing or worrying about formatting is the last thing you want to

Charlotte McCrudden, Independent Law Firm Marketing and Business Development Consultant, Istanbul



Having a constant flow of trivial but often urgent tasks (such as proposals, tenders, and submissions), I do feel a lack of time for more strategic things. This is why I would appreciate having more help with enhancing our legal experience database.

I strongly believe that the transactional background of the firm is one of its core values. Therefore, it would be helpful to have more time for our legal experience management – systematically add new matters, create more detailed and sophisticated descriptions for new and existing matters, track the progress of our work and reflect it in project descriptions, issue subsequent press releases, prepare related descriptions for legal rankings, and advertise our main achievements. The

smart management of the legal experience (which requires a lot of time!) is necessary to produce instant and quality proposals and simplify legal directories management.

Olga Bezverkha, Marketing Manager, Redcliffe Partners



I find important that law firms do not just invest into qualified people but also in sophisticated IT systems. In general, many law firms focus on how lawyers should do their work more efficiently, but my experience is that very few law firms pay the

same attention to back office systems – even though, if in place, they can lead to large gains in efficiency.

Everyone who has ever worked in a support role in a law firm knows that it is not just lawyers' work where there is room for optimization in the organization. Students, assistants, Human Resources, Marketing, we are all in the same group, which often receives feedback on mistakes in first drafts of documents, or comments about the long time it takes to send "a simple list of the names and mailing lists." But when you are using tons of excel spreadsheets to create billions of cells which no one except you can understand, instead of using one efficient system, it is hard – often impossible – to do your work on time and without mistakes. We could be here all day long and

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it wouldn't be enough.

"You don't have to discover America," as we say in the Czech Republic. There are plenty of systems which are tailored for law firms, focusing exactly on what we need. You can't expect miracles from people if you won't give them the tools they need. It's the same as wanting a lawyer to deliver a due diligence project but giving him just a pencil with broken graphite and greasy paper and telling him that whenever he needs to search paragraphs he has to visit a library which is kilometers away. You wouldn't do that, right? So why do lawyers think that we are magicians? We all just want to execute our tasks perfectly.

Libuse Hasincova, Marketing & Business Development Specialist, Glatzova & Co.



It's becoming increasingly difficult to keep up with various yearly and quarterly reporting on deals closed and mandates won. Submission forms for various law firm directories keep growing in number of pages and type of info requested; deal

of the year awards keep popping up, bringing along their own forms and criteria; the entire process is becoming completely time and energy consuming. What was once the best part of my job is becoming the most dreaded time of the year.

Jelena Bosnjak, Business Development & Marketing Manager, CMS Croatia



It's events and legal directories (last minute changes and technical issues, I would say).

Oksana Buchatska, Marketing and Business Development Manager, DLA Piper Ukraine

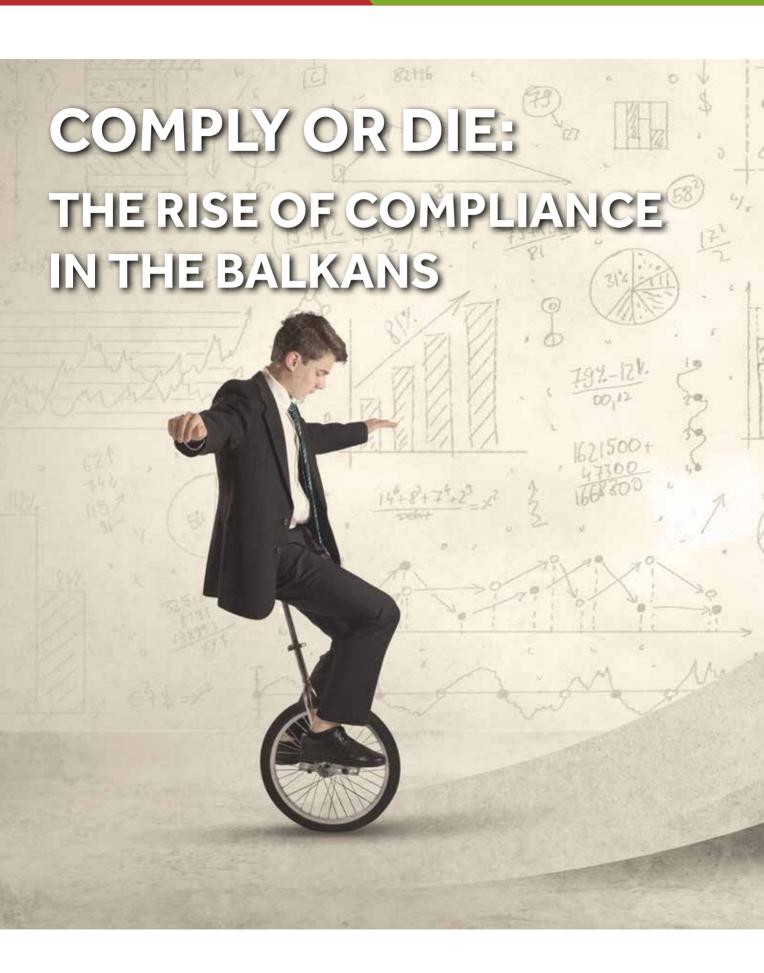


If I had more time, I would love to seek more inspirations for our law firm in terms of the selection of gadgets and other marketing materials, venues for conferences, etc. Also, I would like to spend more time on the improvement of

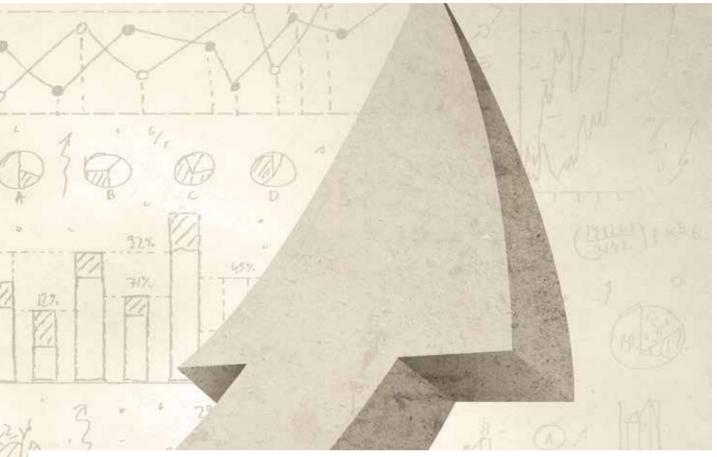
our internal communication and I would like to organize more team building activities.

Daniela Otto-Ziarkowska, PR, Marketing & Business Development Specialist, Jara Drapala & Partners

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COMPLY OR DIE JULY 2019



When it first appeared, the compliance field seemed little more than "regulatory" in new clothes – a fancy name for making sure a company stayed within the ambit of provisions set out in the laws of a country. As time passed, however, more and more companies started treating compliance as a practice in its own right, and as a field of law ... that is much more than just law. Compliance became an area of interest not only to seasoned lawyers, but also to scholars, consultants, and in-house counsels – all levels of legal practice became aware of its significance.

Today, compliance is mostly tackled on two levels: first, it means ensuring that the company meets and satisfies all applicable external rules and regulations, and second – and perhaps more importantly – it means devising and implementing internal systems for educating employees and controlling the level of harmonization with those externally-imposed rules.

In other words, no longer is it expected

that compliance simply means "ensuring that work is done in accordance with the provisions of the law" or that it is a mere renaming of the regulatory practice. And the awakening to compliance that has swept through much of Europe has happened in the Balkans as well.

The Balkanization of Compliance

New legal trends often get a mixed response from legal practitioners and general counsels in the Balkans – a unique combination of countries inside and outside the EU, each of which moves at a different pace. However, on the subject of compliance, it appears that most of the core Balkan countries are in sync – the field arrived at the same time, and in similar ways, and legal counsel have embraced it in a similar manner.

"Compliance should really be a crown on top of all the work put in."



Milos Tanjevic

First, it's worth remembering that compliance involves more than a simple conformity with the law. "The legal dimension of compliance is just one of the planes it manifests itself in," says Milos Tanjevic, Head of Compliance with Uni-Credit Bank Serbia in Belgrade. "When you start assessing certain risks to the company you most often do start with a legal provision, but it frequently grows beyond it." According to Tanjevic, as a first step it is "important to assess if this

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legal provision entails a certain technical standard be met, if the employees of a company are all aware of it, and if company projects are run with this in mind, etc."

In other words, Tanjevic says, compliance is becoming "more and more technical" and it requires expertise in "many fields other than law – for example, IT, economy, and management," in order to provide adequate risk assessment for the company while keeping client satisfaction in mind.

"Compliance should really be a crown on top of all the work put in," suggests Ina Medunic, Head of Compliance with Partner Bank Croatia in Zagreb. Medunic says she has worked "in courts, law offices, and corporations," all of which she credits with giving her a broad overview of both the EU and the Croatian legal systems. This overview, she says, allows her to "easily locate the legal provision with which to begin further analysis and locate any potential problems." In her opinion, this is precisely what "compliance is all about: determining implications of actions and understanding their full impact." And to do this effectively, she says, understanding various perspectives is critical.

Medunic suggests that Croatia may be a step ahead of some of its Balkan neighbors in recognizing the importance of the compliance function due to its membership in the EU. "It was thrust upon us, in a way – but not a bad way," she says. "The EU realized about a decade ago

that companies, and credit institutions in particular, require a position that would have an overview of the entire business operation," she says, maintaining that this includes "being ahead of the curve, sensing in which direction the regulations may move next, and planning accordingly."

In contrast, Tanjevic suggests the arrival of the compliance function in Serbia may have come about "as part of a natural process." According to him, "given that a lot of the relevant legal provisions are not unified in a single act in Serbia, most norms were implemented pro forme until a while ago, with a lot of companies having an optimism bias, but this is not the case anymore." Tanjevic reports that the change was first felt in companies that operate in highly regulated industries such as finance, tobacco, and pharmaceuticals. He hopes that this will, in time, help other companies realize that sometimes "the abstract value of being prepared for all risks," may lead to the "real value" of not having to suffer consequences in the form of fines ... or worse.

Challenges in Adoption

Whether arriving via EU membership or sua sponte, compliance in the Balkans faces challenges - mostly because many in the region have yet to become fully aware of it. "People are still getting to grips with what it means, especially if they never had any contact with it," says Medunic, about Croatia. "The compliance officer position is developing, in a way, along the lines of a similar path that internal auditing has." She says that there aren't "a lot of qualified professionals in Croatia in this field right now, which may very well be due to the fact that the regulators aren't sure what they want yet, but the general trend is definitely expanding compliance beyond the regulatory element."

In Serbia, things are not much different. "We're in a prime position to attract investors with a 'woke' compliance practice, especially if the economy continues to recover and grow," says Tanjevic. However, he reports that "not a lot of legal professionals are aware of the significance of

compliance" and that people in general do not realize how serious the impact of sensitive legal provisions can be.

Tanjevic suggests that part of the problem may simply be that different people have different understandings of what the word means. "Compliance should first have an agreed-upon definition before we can talk about any qualifications for it," he says, noting that the fact that compliance experts operate "sometimes on their own, sometimes in teams of 15," indicates the diverse understandings different companies have of its significance. In addition, lawyers from big law firms aren't always sufficiently up to speed on the importance of compliance either. According to Tanjevic, they often "lack the necessary perspective for expert compliance work - they are on the outside looking in, and they simply can't grasp all the non-legal dimensions of it."

"Well, to be honest, compliance wasn't a big thing in the region until a few years ago," says Nevena Perovic, Head of Legal and Compliance at Lidl Serbia. "With the increase in the number of large international corporations, like Lidl, compliance kind of trickled down to the Balkans, which is why most of the experts in this field are to be found in-house, rather than in law firms." Perovic believes that "compliance differs significantly from other legal practices. It is much more than having the legal department provide an answer to a question – it's about creating a mindset of compliance, which is a much broader thing."

"This is precisely why a compliance officer must be much more than a lawyer — this person needs to know how the entire system works, not just the legal aspect of it. It's a bit like with specialist doctors — a good cardiologist still needs to understand how the whole body system works in order to be good at his job."

COMPLY OR DIE JULY 2019

Perovic thinks that "to ensure the growth of compliance, the market should attract more young people to compliance as a field of legal practice. The educational sector, be it mainstream or alternative, must continue with conferences, gatherings of professionals, and training courses that aim to raise awareness of compliance and offer insight into how one might grow professionally within this field."

How Will It Grow?

Reflecting the relative novelty of the function, there's still significant overlap with simple regulatory oversight. "It mostly depends on the corporate environment," says Medunic. "However, it comes down to what are they doing, essentially."



But in her opinion, the compliance function – as something above and beyond regulatory – is extremely important. "The problem is that the current legal framework, both in EU and in Croatia, is in a state of development," she says. "This is precisely why a compliance officer must be much more than a lawyer – this person needs to know how the entire system works, not just the legal aspect of it. It's a bit like with specialist doctors – a good cardiologist still needs to understand how the whole body system works in order to be good at his job."

Still, Medunic points to the growth of the field in recent years – and predicts even more growth to come. The markets in the region, she says, are "still doing some soul searching, and new functions and positions are being defined, and compliance

does not lag behind." According to her, "if legal professionals wish to become compliance experts, they need to broaden their views and fields of interest. It goes beyond just the regulatory scope which most lawyers may currently equate with compliance. When the business owners themselves realize this, there is no doubt that compliance will be more invested in, and then we'll see it blossom."

"Small companies in the market, be it the Balkans or Serbia, are in an unfavorable position for efficient compliance uptake," says Perovic. "What is definitely true is that installing a compliance function possesses the potential to better a company's reputation, which may lead companies to invest in its growth sooner." In other words, Perovic says, this "reputational" motivator may be just as strong as a more "reactionary" one, which sees companies investing in compliance to avoid suffering a negative event they have seen happen to one of their competitors.

Perovic also believes that investing in compliance for positive image reasons, in order to instill faith in a company's customers, will prove to be a strong motivator as well. "If a company has a strong compliance culture then it is ahead of the curve. This sends a clear, positive signal to its partners, clients, and customers — both real and potential."

Milos Tanjevic, on the other hand, is a little less optimistic. He believes that "the path compliance has before itself is a very thorny and painful one, but one that must happen." In the meantime, he believes that compliance officers will struggle with insufficient institutional support and recognition until companies, legal consultants, law offices, and the academic community realize the "importance of compliance and take an interest in commenting on it and investing in its development further in the Balkans." Still, he believes that, once this path takes hold, more and more "lawyers will get in on the action and will wish to take part in creating new services that they could offer to their clients." Ultimately, he says, companies will have to "evolve to comply - or die in the process."

"If legal professionals wish to become compliance experts, they need to broaden their views and fields of interest. It goes beyond just the regulatory scope which most lawyers may currently equate with compliance. When the business owners themselves realize this, there is no doubt that compliance will be more invested in, and then we'll see it blossom."

Tanjevic reports that Serbia will soon get its first Compliance Association to serve as a cross-industry hub both for lawyers and professionals from other highly regulated industries such as the pharmaceutical industry, telecommunications, tobacco, and the like. He says that the Association will focus on "business ethics as the underlying factor of efficient compliance," and that it will "further the sharing of know-how, as well as its improvement by exchanging best practices," and "spread the awareness of compliance among both professionals and the general public."

It appears that, although the road to further acceptance may not be smooth and fast, compliance in the Balkans is growing as a legal practice. More and more legal professionals are waking up to its importance and more companies are attempting to get in on it early – rather than waiting until it's too late. For these countries compliance may have started as "simply following trends" but it is evolving beyond that, to following best practices that are much wider, all in order to nurture forward thinking and help compliance officers prevent the worst.

In following the lead of those companies with dedicated compliance functions, other companies in the Balkans may want to – dare we say it? – comply.

Andrija Djonovic

JULY 2019 LEGAL MATTERS



In the second of our series counting down to the April 23, 2020 Dealer's Choice Law Firm Summit – the first ever major conference in London for lawyers and law firms from and interested in Central and Eastern Europe – we reached out to three sponsors to learn more about their hopes and expectations for the event.

■ Mykola Stetsenko,

Co-Managing Partner, Avellum, Dealer's Choice Sponsor for Ukraine

■ Peter Berethalmi,

Partner, Nagy es Trocsanyi, Dealer's Choice Sponsor for Hungary

■ Vladimir Bojanovic,

Partner at Bojanovic & Partners and member of the Adriala law firm alliance in South East Europe

CEELM: First, for our readers, can you each tell us a little about your firms – their backgrounds and profiles?

Mykola: Well, Avellum is a full-service law firm and our key focus is on Finance, Corporate, Dispute Resolution, Tax, Real

Estate, and Antitrust. We aim to be the firm of choice for large businesses and financial institutions for their most important and challenging transactions.

Peter: Nagy es Trocsanyi is one of the largest, home-grown independent law firms in Hungary and we celebrated our 25th anniversary two years ago. We are an exclusive Lex Mundi member firm and provide services to multi-national and domestic companies in various fields. Our firm is well-known internationally for its dispute resolution and transactional work capabilities. We have an extensive Energy practice which included our participation in the Paks 2 project and various other energy projects including thermal and solar energy. We also provide advice regularly in Real Estate and Banking and Finance matters.

CEELM: And Vladimir, tell us about Adriala.

Vladimir: Adriala is a unique business

law firm alliance of independent premium law firms based in nine jurisdictions in SEE, distinctive from any other local law firm or legal network in its approach to clients. Adriala was founded in 2016 and since then has enabled member firms to, among other things, handle international projects seamlessly throughout the South-East region. All of the Adriala independent premium law firms from Albania, Bosnia and Herzegovina, Bulgaria, Croatia, Kosovo, Macedonia, Montenegro, Serbia, and Slovenia are ranked top tier, based on their expertise, professional and pragmatic approach to business issues and legal services tailored to client needs. Being independent is a major factor in ensuring quality control. Instead of expansion from one centralized headquarters, we focus on delivering locally while ensuring the highest quality of service in jurisdictions where we operate.

CEELM: Let's stay with you, Vladimir. Why did Adriala decide to sponsor the Dealer's Choice event?



Vladimir: We think that the Dealer's Choice Conference is a perfect event combining topics of importance to the legal profession and a gathering of people from various law firms across the globe. We think this is a great opportunity for Adriala to contribute to this amazing event and to exchange views and ideas with others in an entertaining way.

CEELM: And Mykola, what about Avellum?

Mykola: The Dealer's Choice event is a great opportunity to meet leading practitioners and in-house lawyers in the CEE region. We enjoy building strong connections with our colleagues in the region and have been attending CEELM events for a number of years. Thus, sponsoring this event in London was a natural choice for us.

CEELM: What about you Peter? Why did Nagy es Trocsanyi think it important to sponsor this?

Peter: We first of all wish to support CEELM as a leading international legal publication in its efforts to market and promote the Central European legal market and we think that for us, as a leading Hungarian domestic firm, the Central European legal market is important. Also, we wish to demonstrate our capabilities in the region with our extensive network of friendly law firms in the region.

CEELM: What topics would your firms be interested in seeing addressed at the event?

Mykola: I am personally interested in the debate around automation and AI, as well as better practices for people management.

Peter: We would like to see something addressing the challenges of the legal market in general and the particular challenges of the region.

Vladimir: For us, there are various topics of interest, ranging from Artificial Intelligence, M&A and Banking and Finance, Competition, and Energy-related topics to cross-border enforcement of IP Rights.

CEELM: How much of your business would you estimate comes via referrals from international firms - and how do you keep that pipeline flowing?

Mykola: I would say that roughly 25% of our business comes from referrals from international law firms. We believe that keeping in touch is very important, but delivering really high-quality legal advice on time is the key factor for our referral sources. These law firms and their clients really like our approach to work.

Peter: I would estimate that 20-30% of our work is generated by international firms but this number alters from time to time. We make a concerted effort to maintain our working relationships through various channels.

Vladimir: We would estimate that a significant percentage of all Adriala business comes via referrals from international law







firms, somewhat less than locally-sourced work and regional referrals. Additionally, we would like to point out that in the past year we have strengthened our relationships with big international law firms and we try to maintain and develop these relationships.

CEELM: Thank you all. We are delighted you will be helping us shape the agenda to make Dealer's Choice a massive success next year in London!

Maria Bredican



AUSTRIA JULY 2019

GUEST EDITORIAL: AN OVERVIEW OF THE LEGAL MARKET IN AUSTRIA

There are two interesting developments on the Austrian legal market: First, Legal Tech and Digitalization initiatives are on the rise. Second, the Top 20 law firms in Austria have increased their revenue last year, and the legal business is flourishing.

Legal Tech

Digitalization has influenced most areas of everyday life and is increasingly entering the Austrian legal market.

Austria set a world-wide example in 1990 when the Austrian Ministry of Justice, in cooperation with other Austrian entities, launched the ERV platform, allowing for a streamlined electronic exchange of communication between courts and parties. This has led to considerable savings so far (for instance, EUR 12 million in postal charges was saved due to the ERV platform in 2016 alone).

In order to further boost legal tech initiatives made in Austria, seven major Austrian law firms have joined forces to establish the Legal Tech Hub Vienna (LTHV), dedicated to promoting ideas and solutions in the field. The overall goal of LTHV is first and foremost to extend the range of services to clients by introducing new automated processes and additional digital services. One of the key initiatives in this context to make sure that the LTHV will soon start is a so-called "accelerator program" designed to create tighter collaboration of law firms with legal tech start-ups and SMEs.

Another frontrunner on the Austrian legal market is the Legal Tech Initiative Austria, which regularly organizes events for lawyers on topics such as smart contracts and which recently organized the Vienna Legal Tech 2019 conference to increase the awareness of new developments in the tech area which could be applied to the legal market.

During the past few years some of the several legal tech startups which have been formed have been quite successful, and the technologies they have created have been implemented by a number of law firms. For example, the Austrian legal research tool LeReTo, which automatically provides users with a list of all legal references in a judgment or an appeal, thereby saving lawyers many hours of research, has become widely used in the Austrian market, and the company has already expanded to Germany.

Out of a concern that the attorney-client privilege is regularly challenged, given that email, the main communication medium between attorneys and their clients, is in most cases not very secure, particularly when involving cross-border communication, the Austrian Bar Association has initiated the development of a tap-proof communication channel which Austrian lawyers may use



for their communication with clients. Some of the larger law firms have already developed individual solutions as well by making use of platforms which allow for a secure exchange of business data.

One thing is for sure: the legal market will be revolutionized by new legal tech developments, particularly when it comes to standard contracts, and it will be interesting to observe how technologies made in Austria will succeed in the market.

Performance of Austrian Top Law Firms

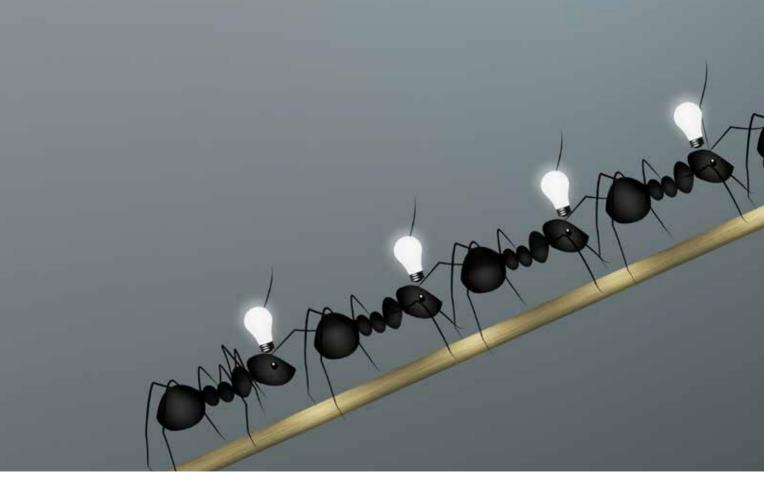
Last year was once again a successful year for the Austrian legal market. According to one publication, Austria's Top 20 law firms accounted for an increase in their revenue of around 2.8 percent on an aggregate basis in 2018 – approximately the same growth as the preceding year. Most of the Top 10 law firms were able to increase their revenues in 2018, with one of them leading the way with 12.9 percent. The twenty largest Austrian law firms employed an average of 60 lawyers in 2018, with an average annual turnover of approximately EUR 415,000 per lawyer. The five largest law firms in Austria each employed around 100 lawyers.

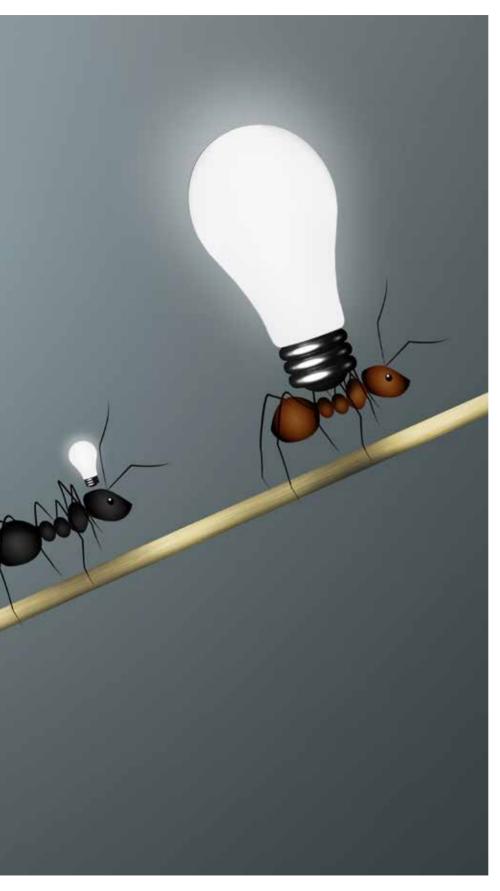
There were 6,325 lawyers and 2,215 trainee lawyers in Austria as of December 31, 2017. Around 22 percent of the lawyers and 50 percent of the trainee lawyers were women. Still, women are rarely to be found on equity partner level. While more and more women have been promoted to contract partners in recent years, there is still a big gap compared to the number of women making the leap to equity partnership. On the other hand, for the first time, two of the leading Austrian law firms – one of them being Dorda – have recently promoted a female equity partner to their management boards. Furthermore, the Top 10 Austrian law firms are increasingly pushing women's promotion programs in an attempt to close the still-considerable gender gap soon.

Martin Brodey, Partner, and Patricia Backhausen, Associate, Dorda

BEHIND THE BENEFITS

How do law firms in Austria promote themselves to current and prospective employees? A series of conversations with several leading firms revealed more than expected.





The American humorist Will Rogers once wrote that "a difference of opinion is what makes horse racing and missionaries." It also makes law firm management, and the varying law firm cultures and working environments that firms promote both internally and to the outside world.

We recently spoke with partners at four leading law firms in Austria – Dorda, Knoetzl, CMS Reich-Rohrwig Hainz, and Schoenherr – to learn about the differing benefits and workplace amenities their firms provide for their employees. And in addition to the benefits themselves, what these firm representatives chose to emphasize revealed a great deal about the ways the firms promote themselves to the market, and the way they see themselves and their colleagues.



Dorda: Commitment to Professional Development

Dorda Partner Christoph Brogyanyi is effusive, enthusiastic, and confident about the benefits Dorda offers its employees, and he quickly turns the conversation to the developmental opportunities the firm provides young lawyers joining it out of law school. First and foremost, Brogyanyi rejects the misperception he says many fresh Austrian graduates have that working at a bigger law firm means being forced to specialize immediately, potentially damaging their ability to pass the wide-ranging bar exam. At least at Dorda, Brogyanyi says, young lawyers work across several practice areas and learn about a broad cross-section of law firm work. "We have to fight the preju-

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dice that you will have to specialize immediately," he said. "And we tell them this, and we have to promote this as well. What they want is in-depth education, but at the same time not to be railroaded into one direction and being totally silo'd. We have to emphasize that, because you sometimes hear rumors that '24-7 I only do M&A deals,' or 'I only do financing and stuff,' and this is something that may scare off students that haven't really decided which direction they want to go."

Brogyanyi insists that Dorda is known for its commitment to continuing education and professional development. "We focus on education a lot," he says. "I think we are perceived on the market as a firm that does that and focuses on that. And therefore, a whole bunch of benefits we offer our associates focus on professional development." As an example, he points to the Dorda Academy, which he describes as "a series of short seminars in spring and autumn every two to three weeks where partners and other experts speak about certain areas of law to give practical expertise to new lawyers who have finished university but who have a primarily theoretical experience and to provide information about certain areas of law that they may not have learned about in university."

That's not the only kind of ongoing ed-

ucation Dorda provides, Brogyanyi says, noting that "lawyering is not only being good at law but also how to deal with clients, how to present yourself, rhetorical skills, and how to negotiate, [so] soft-skill trainings are something we also offer on a regular basis."

And Dorda's commitment to professional development includes significant practical experience as well, Brogyanyi reports, including allowing "even young associates to get client contact, go to court, etc." He says, "it's my impression that there are some firms out there that would not let a second year or first year associate be in contact with a client immediately, or the court, or whatever authority you have to work with." With Dorda, he says, "you can go with us to the meetings, you participate in telephone conversations, you are in contact with courts and authorities, and stuff like that. We highlight that in our recruiting meetings with the students."

Brogyanyi describes surprisingly progressive attitudes towards a work/life balance at the firm as well. "What we try to offer is flexible working time," he said. "This doesn't mean you can come whenever you want, of course. But if you want to work half time, or 70% or whatever, this is a fine deal for us. Just tell me in advance

and we will accommodate that." He nods vigorously when asked whether lawyers at the firm actually ask for this option. "Obviously first-year and second-year don't often take advantage of this opportunity," he says. "But we have some associates who are fathers or mothers already or who are working on part of their education, like a doctoral thesis, and they say things like well, four days a week are fine for me, but the fifth day I have to attend classes, or something like that."

In his opinion, this unusual flexibility is part of an overall team spirit. "At the end of the day, this package that we offer leads to a very positive working climate here. So all the associates are basically working as a team, and they tend to help each other to a great extent. Over time, this give/take is something that is quite special to our firm. This helping relationship is top-down, and bottom-up, basically, and it happens all the time. And that helps us give the flexibility in working hours and working days."

Only at the end of the conversation does Brogyanyi turn to the firm's social programs. "We have an annual Christmas party, and a summer party, where we take a whole day off, take the whole firm, and take them somewhere in the area. We've done paintball and volleyball, and things like that. This is highly regarded. And it ends with a big party. We also do one outing a year for the Wiener Wiesn-Fest – the Austrian Oktoberfest - when everyone comes in their traditional outfits. This is a highlight of the year." Finally, he says, there's a monthly round-table party at the restaurant below the office for the entire firm, including staff.

Brogyanyi is asked how he would describe Dorda as a place to work. "I think it's a very friendly environment," he says. "We try to make it possible for everyone to focus on what they are working on here. We are people with humor. We don't take ourselves too seriously. We know that we have to work on serious matters and deliver high quality, but in order to achieve that it is necessary to have a comfortable working environment."



Knoetzl: Focus on Employee Satisfaction

Unlike Brogyanyi, Knoetzl Managing Partner Tim Pfister quickly turns the conversation to the many efforts his firm makes to ensure that each of its lawyers are respected, heard, and valued.

"We have a lot of concern about the care and feeding of our people," Pfister says. As an example, he cites the firm's annual Tombola - a Christmas-time raffle. "Our senior founding partner came from a firm where she thought it was not all that in the spirit of the season when the firm management walked away with a bundle of expensive goodies, and took them home," he says. "The staff saw that, and didn't have any shot at it." At Knoetzl, he says, "all those gifts that are given by vendors to the partners at Christmas time are put under the Christmas tree, and people draw for them in a Tombula." He waves his hand. "It's not a big deal," he laughs. "But it is a good reflection of our philosophy."

Pfister says that he personally takes the lead on two employee satisfaction programs at the firm. First, he says, "I have an annual, face-to-face meeting with every employee of this law firm – from the most senior founding partner to the guy who has accepted but has not yet started as a part-time messenger – to ask them 'how are we – the firm – doing for you, and how can we improve?' It's an interesting process, and I try very hard to implement whatever suggestions are made."

In addition, he says, he leads a "Drinks With Tim," campaign, taking different groups of 5-6 lawyers at a time out for drinks over the course of a year. "It's not a review," he smiles. "The topics are such things as 'what is it like, and what is like relative to your expectations, to be a lawyer?', 'wait! ... what???,' and even 'where in Vienna can you find the best steak?""

Pfister reports that Knoetzl takes many opportunities to celebrate firm successes with parties in the lounge that was specially designed for the purpose, or on the firm's rooftop terraces. "We believe that it's important to celebrate our wins, our good news, our births – we just had our first firm baby," he laughs. "Parties on the terraces or around the staff-use part of the reception floor. That doesn't come free. And the reason we do that has nothing to do with our clients. We do it exclusively for our employees. We specifically chose these wonderful premises to give our employees a pleasant place to work."

Knoetzl, Pfister says, like the other leading firms in Vienna, schedules several major social events a year. "We also have external gatherings from time to time," he says. "Like the "Weinwandertag, where we walk – and drink! – through the vineyards of Vienna's 19th district." In addition, he adds, "we also make a point of getting together in the summer for outings, and we

have a Christmas party somewhere off campus."

Knoetzl's American-born Managing Partner – himself an avid American college basketball fan – brought a little bit of his home country to the firm as well. "We have an office NCAA basketball pool," Pfister laughs, "in which everyone has become comfortable – even enthusiastic – about playing." He notes with pride that his favorite team, the University of Virginia, won this year's tournament (leading Knoetzl Office Manager Philipp Hirschauer to add, regretfully, that he chose Duke). "We also have a soccer one and we plan a skiing pool."

Pfister finds it difficult to articulate a specific law firm culture or environment at Knoetzl. "There's not a uniform answer to that," he says, reflecting. "Because lawyers are individuals, and individuals are – and are encouraged to be – different from one another. That's probably something, in my charge to make this more like a Wall Street firm, that I need to reinforce over time."

In the meantime, he says, "all we say to recruits is that we look for people who are both 'gut and gut' – that they are both good and excellent. Good people, and excellent lawyers. That's it – that's what we're looking for."



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CMS Reich-Rohrwig Hainz: Confident with the International Profile

Partner Gunther Hanslik feels that extra benefits are beside the point at the Vienna headquarters of CMS Reich-Rohrwig Hainz. "First of all, I really genuinely think we don't have to do much to make it a good place to work," he says, smiling. "People like working here, because they like the team spirit, they like the premises, the atmosphere, and international aspect. And that's what we really want them to experience as well."

Hanslik notes that CMS's international footprint provides associates with options and opportunities they cannot get at purely domestic law firms. "We regularly send young lawyers to international CMS Associates meetings and CMS trainings," he says. "These programs are organized by the practice groups, and most do it annually, or every 18 months."

CMS is also committed to the professional development of its lawyers, Hanslik says, pointing to a professional development program similar to the one Christoph Brogyanyi described at Dorda. "CMS has a program called the Core Curriculum for juniors and seniors," Hanslik said, "and then later on for junior partners and even senior partners. We don't just focus on technical stuff, but also soft skill trainings and personal development trainings."

Ultimately, Hanslik believes that CMS's commitment to professional development and international training is the key selling point. "All that means we don't have to do too much besides that."

Still, he concedes that the firm does sponsor several purely social events, including CMS's annual firm-wide soccer tournament (held in a different country each year, with over 500 young lawyers participating), an annual firm-wide Christmas party (involving all the lawyers from Reich-Rohrwig Hainz's ten offices in South Eastern Europe), and an annual July event specifically for the Vienna office. In addition, he says, the firm brings in a

masseuse once a week for lawyers seeking to destress, and provides a membership discount at the nearby health-club.

Still, Hanslik insists, an over-emphasis on frills risks distracting lawyers from the task at hand. "For me it's a little bit about being authentic as well," he said. "It is after all a professional service place, where we focus on making our clients happy. It can include long hours, work on the weekend, and so on. And so we focus on people who love being lawyers and love working as lawyers. Plus our philosophy is that it's more important that the working atmosphere is good, the teams work well together, in the sense that they enjoy working together."

Hanslik's answer to how he would describe CMS's culture is short: "Friendly. Open."



Schoenherr: Creature Comforts

Schoenherr Director of Business Operations and Director of Marketing Birgit Telsnig is enthusiastic about the various ways the Schoenherr office itself encourages cooperation among lawyers and a facilitates what she describes as a healthy, mentally sound staff, pointing as examples to an in-office gym, several dedicated nap rooms, free branded bicycles and scooters, and more. She starts the conversation with a tour of the office, which the firm moved into in 2014.

"We don't own the building, we rent it," Telsnig explains, walking through the

firm's impressive fitness area. "And when you rent, you need to utilize the available area in the best way possible. As part of our health and employee benefits, we decided to use the additional space for a fitness studio with showers." There's more. "Four times a week a trainer comes, in the evening, and they offer free training for everyone," Telsnig says, happily. "You literally can come here 24/7. Even on weekends. And our lawyers really enjoy, when their heads are really full, they can come down here, have their training, have their run, and then go upstairs again. It's a really nice added value."

"We want to get rid of this dual-class thinking. Everything is for lawyers and business professionals. Everyone has an important role. If one doesn't fulfill his or her tasks, the whole surrounding doesn't work anymore. Both lawyers and business support are included in our education systems and programs."

Telsnig insists that the firm's three dedicated nap rooms are less unusual than they may seem. "Power napping is very normal in other countries. It's just very normal. And we also don't think it's a big deal." Ultimately, she says, "it's not about keeping people here for longer working



hours. It's just giving them the chance to relax. We want to create a real collaboration space."

Schoenherr Managing Partner Michael Lagler points out that the various benefits are not reserved for the firm's lawyers. "We want to get rid of this dual-class thinking. Everything is for lawyers and business professionals. Everyone has an important role. If one doesn't fulfill his or her tasks, the whole surrounding doesn't work anymore. Both lawyers and business support are included in our education systems and programs."

Like other firms, Schoenherr organizes regular social events. Lagler describes a firm Happy Hour, held four times a year at a watering hole across the street, as "one of our most liked programs. Where we just say come, and meet." And the firm's annual Christmas Party, attended

by lawyers and business support personnel from all 14 of the firm's offices across CEE, is legendary both inside and outside Vienna. According to Lagler, "we like it – we like to have a good environment. We're not a firm that wants people coming in and having no personal life anymore."

Lagler is asked how he would describe the firm's culture. "I mean culture and values – these are always kind of mixed up," he says. "But the main firm culture is that people understand that we are a group of people who want to give the best on a day by day basis, and this is only possible if we work together."

It's All About Choice

"Excellence is never an accident. It is always the result of high intention, sincere effort, and intelligent execution; it represents the wise choice of many alternatives - choice, not chance, determines your destiny."

- Aristotle

The way the lawyers we spoke with chose to direct the conversations reveals something about their priorities, and it illustrates the different ways top tier firms can promote themselves, both internally and externally.

It goes without saying that the aspects of their firms the individuals we spoke with chose to emphasize does not mean that other aspects do not exist. Indeed, each of the firms we spoke with has achieved its position on the market through a combination of — in addition to highly-deserved reputations for skilled, consistent client service — employee retention efforts, professional development opportunities, good office environments, and a commitment to employee satisfaction.

Still, the various packages the firms offer and the way they describe their focuses creates intriguing variety for fresh graduates and prospective employees. In other words: Where would *you* like to work ... and what kind of culture would *you* create?

David Stuckey



MARKET SPOTLIGHT



The Deal: Earlier this year, CEE Legal Matters reported that Herbst Kinsky Rechtsanwalte had advised Marinomed Biotech AG on its February 1, 2019 debut on the Vienna Stock Exchance, with Weber & Co. advising Erste Group Bank AG (as sole global coordinator) and Goetzpartners Securities Ltd (as co-lead manager) on the IPO. Marinomed's was the first successful IPO in Austria since BAWAG's in 2017.

The Players:

- Counsel for Marinomed Biotech: Philipp Kinsky, Partner, Herbst Kinsky
- Counsel for Erste Group Bank and Goetzpartners Securities: Christoph Moser, Partner, Weber & Co.

CEELM: Philipp, can you tell us what exactly Marinomed Biotech is?

Philipp: Marinomed specializes in the development of innovative products based on patent protected technology platforms in the field of respiratory and ophthalmic diseases. Marinomed has developed two platforms to date: the Marinosolv technology platform and the Carragelose platform. The Marinosolv technology platform enhances the efficacy of hardly soluble compounds. This innovative technology has the potential to sustainably change a number of therapies for allergies and auto-immune diseases. The flagship product, Budesoly, is currently being investigated in a pivotal Phase III approval study. The Carragelose platform is already used in six different products –

sold globally via the company's partners – to treat viral infections of the respiratory tract.

CEELM: And how did you and Herbst Kinsky become involved with helping the company in this matter?

Philipp: We have been legal adviser to Marinomed since its foundation in 2006, so based on this longstanding and profound relationship and due to our reputation in the capital market law area Herbst Kinsky was the logic choice for Marinomed. A high level of trust connects us with founders Andreas Grassauer and Eva Prieschl-Grassauer. Knowing what Marinomed means for the founders we are especially proud to be chosen as the company's legal representative.

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CEELM: And Christoph, how did you and Weber & Co. become involved?

Christoph: The assignment of our firm for the IPO is the result of trusted relationships with national and international investment banks and a long-standing track record of advising banks as underwriters and bookrunners on Austrian equity capital market transactions. Our firm is well known in the market as a goto-firm for underwriters in ECM matters. Further, the IPO assignment was a follow-up assignment to the issue of pre-IPO convertible debt instruments by the issuer back in 2017, when we also worked for Erste Group Bank AG as arranger's and sole coordinator's legal counsel. In that 2017 transaction, Philipp Kinsky was involved as issuer's counsel as well.

CEELM: What, exactly, was the initial mandate when you were retained for this project?

Christoph: The initial mandate did not change later. But of course during an IPO process lasting for more than three quarters of a year new issues and tasks always pop up. As an experienced ECM lawyer you know the rules of the game and are aware that in particular transaction structures and involved parties may change. However, the focused and wonderful Marinomed Biotech team knew right from the beginning that they want to go for an IPO and all parties involved ensured that even after rough capital market developments in October and November 2018 the transaction could be completed in early 2019.

Philipp: Herbst Kinsky was mandated in the course of the convertible bond issuance in 2017; as this bond included the right to convert debt into equity

upon an IPO, initial preparations for the IPO commenced soon after the issuance of the convertible bond in 2017. Initial preparations also included the development of a legal structure to convert existing silent partnerships held by ARAX.

CEELM: What is ARAX?

Philipp: ARAX Capital Partners manages several funds (limited partnerships, predominantly funded by private investors) that invest in Austrian tech and life science companies via silent partnerships. Those partnerships become repayable by the target companies upon certain conditions. To retain as many IPO proceeds as possible for the company's operations, Marinomed and ARAX agreed on the conversion of the silent partnerships into equity (instead of repayment of silent partnerships) by transferring shares from existing shareholders to ARAX funds against contribution in kind of their silent partnerships into Marinomed.

CEELM: Who were the members of your teams, and what were their individual responsibilities?

Christoph: Our Weber & Co. team consisted of a mix of partners and associates, all with significant experience in capital market transactions. I took over the overall project lead and transaction structuring and acted as the central contact for involved parties from the issuer's side and our client banks' side. Further, I supervised the responsibilities for the due diligence, prospectus, and documentation work on the banks' side. Our firm's team also included Partner Stefan Weber, who contributed in particular on matters related to the underwriting agreement, as well as Associates Angelika Fischer (who jointly took over the project management

lead with me), Yvonne Gutsohn and Clemens Nostler.

Philipp: Our team at Herbst Kinsky consisted of partners and associates specialized in capital market law, as well as IP experts and an employment lawyer. I have been in the capital market business since 2000, and I led and supervised the team. I was supported by our new partner - Philipp Baubin - who was responsible for drafting the prospectus. Furthermore, Associate David Pachernegg was in control of the due diligence process and guided our team of Felix Kernbichler, Georg Durstberger and Magdalena Wagner. Our IP/IT Partner Sonja Hebenstreit, with the support of Christina Perez and Alexander Holler, was responsible for all IP/IT related issues in connection with the offering. Tanja Lang was in the lead regarding various employment law matters.

"We never had a better team spirit, internally and externally, in IPO transactions. All involved parties, irrespective of their different views and interests, focused on the success of the transaction, did not engage in any game-playing or useless discussions. This was so unique and I will remember the special spirit among the group for the rest of my career."

CEELM: Please describe the IPO in as much detail as possible.

Christoph: The IPO consisted of a cash capital increase aimed at raising new equity funds for the issuer for developing its product pipeline. It became clear at an early stage that the transaction would not include any sales of shares by exist-

ing shareholders as management and core shareholders believed in the issuer and its future and therefore committed to stay on board and partially also bought new shares in the IPO. Therefore, the transaction structure was set at a rather early stage. The IPO process was commercially managed from the banks' side and in particular Erste Group Bank played a leading role in the support of the prospectus drafting by the issuer and its legal counsel Herbst Kinsky.

On the issuer's side, Philipp Kinsky and his team did a fantastic job managing numerous tasks to be completed, including dealing with all corporate law issues, holding the pen on the prospectus drafting, assisting the issuer and the auditor on the intense prospectus work, managing the due diligence process and ensuring that the conversion of the pre-IPO convertible bond will work in the end after the IPO. As to certain matters of US law, Herbst Kinsky and the issuer were assisted by Clifford Chance LLP Frankfurt, which focused on the US-law-related offering aspects (Rule 144A offering to US investors).

Our firm primarily focused on tasks such as commenting the prospectus, conducting a legal due diligence for the banks' side, commenting on corporate documentation, drafting and negotiating the underwriting agreement, negotiating the comfort letter, issuing legal opinions visà-vis the bank, advising on the offering structure, and taking a lead in the overall transaction management on behalf of the underwriters.

Overall, an IPO provides for numerous tasks to be completed and it was a true pleasure having the right counter-parties on the transaction: a great Marinomed team, diligent, hard-working and experienced lawyers of Herbst Kinsky, an auditor (BDO) who knows the rules of the game and supported with advisory and audit feedback in a stunning way, the experienced US team of Herbst Kinsky and, of course, highly professional bank teams, with Erste Group in particular being true experts for Austrian ECM trans-

actions and IPOs.

Philipp: The IPO process consisted of the several work streams, including the various corporate law measures in connection with the capital increase, the due diligence work, and prospectus drafting, as well as establishing the underwriting documentation between the banks and the issuer.

Another challenge of this transaction was the conversion of the pre-IPO convertible bond and silent partnerships held by ARAX. However, while this was demanding, we also benefitted from the fact that cooperation between the various teams was kind of "tested" and already well-attuned before we entered into the IPO work and that we could also build our work on certain preparations made in the course of work for the Pre-IPO convertible bond (for example, the due diligence and parts of the prospectus documentation).

Throughout the entire process, we have definitely benefited from the great cooperation between the various teams. The Erste Bank team, Clifford Chance as US counsel, BDO as auditor, Weber & Co. as issuer counsel, PR-advisor Metrum, and not least the entire Marinomed team, all did a great job solving the numerous challenging tasks and situations and bringing the project over the finish line against all obstacles, in particular the difficult market environment.

CEELM: What was the most challenging or frustrating part of the process?

Christoph: Due to adverse market conditions, the transaction had to be pulled at the end of the initial offering period in November 2018. It wouldn't have made sense to go to the market in a time where all investors tried to stay out of the markets. For some days, it looked like true turmoil in the market and nobody knew how the situation would evolve in December 2018 and early January 2019. In this situation, Erste Group, Herbst Kinsky, and we found a quite smart, never-before-tested way of keeping the prospectus "alive" by

publishing a supplement and announcing that the transaction was aimed to be re-commenced in early 2019. Technically, the IPO was not stopped but only paused and we were able to convince the Austrian regulator of this new model. This was challenging but eventually a great success for the legal teams of Herbst Kinsky, Erste Group and Weber & Co.

Philipp: One of the most challenging and frustrating situation definitely was to learn that the market environment did not allow for the completion of the first attempt to close the transaction at the end of 2018, so that we had to postpone into January 2019. Another critical point was when Kempen made its last-minute decision not to proceed with the transaction. Quite frankly, there were certain points throughout the process where we had our doubts that the project would be successfully completed in the end. We were very glad and impressed to see how these situations could be solved with joined forces between the teams and a very solution-oriented, hard-working, and flexible approach by everybody.

CEELM: What was Kempen's involvement here?

Philipp: Kempen & Co is a Dutch merchant bank providing financial services in securities broking, corporate finance and asset management. It has built a strong position as dedicated specialist player in the European Real Estate, Life Sciences & Healthcare and Financial Institutions & FinTech sectors. Kempen acted initially as Joint Global Coordinator and Bookrunner together with Erste Group Bank and, following suspension of transaction in 2018, decided not to proceed with the IPO. Erste Group Bank, therefore, became Sole Global Coordinator and Bookrunner of the IPO.

CEELM: Was there any part of the process that was unusually or unexpectedly easy?

Christoph: Yes, the interaction with the involved persons. We never had a better team spirit, internally and externally,

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in IPO transactions. All involved parties, irrespective of their different views and interests, focused on the success of the transaction, did not engage in any game-playing or useless discussions. This was so unique and I will remember the special spirit among the group for the rest of my career. This was truly outstanding and unexpected as we all worked on transactions before were parties primarily focused only on their respective interests but not enough on the overall success of a transaction.

Philipp: Underwriting Agreement negotiations did not end up being too lengthy as Weber & Co., Marinomed Biotech, and we all had a very pragmatic approach to solving legal issues. Also the Comfort Letter discussions went quiet smoothly with BDO as a solution-oriented and very pragmatic partner.

CEELM: Did the final result match your initial mandate, or did it change somehow from what was initially anticipated?

Christoph: Yes, it did, subject only to minor amendments structural-wise and the postponement of the IPO from beginning of December 2018 to beginning of February 2019.

Philipp: Disregarding the fact that things always turn out to be a little more demanding and time-consuming than initially expected and also mostly require certain adjustments of the intended structure and timing, the result finally matched our initial mandate.

CEELM: How successful was the IPO, ultimately?

Philipp: Given the difficult market environment in Q1/2019, the IPO was extremely successful with EUR 22.4 million in proceeds and stable stock price following the IPO (no stabilization measures were necessary within applicable post-IPO stabilization period). Since the first listing, Marinomed's stock price has never fallen below issue price of EUR 75 per share.

CEELM: What specific individuals at Er-

ste Group Bank AG and Goetzpartners Securities Ltd. directed your team's work, and how did you interact with them?

Christoph: Our team worked very closely with the ECM team of Erste Group, which acted as lead manager and were the true stars on the banks' side. They made the transaction happen, never lost faith, and pushed all involved parties to their limits in a positive way. The core ECM team of Erste Group included, among others, Guenther Artner, Markus Koller, Ignaz Bodenstorfer, Karin Heitzing-Daxbock, and Fabian Ketzler, but so many others as well, including the head Bernhard Leder, a great sales team and many more. In such a long process, you work together seamlessly, with numerous telephone calls, emails and meetings. And from my point of view the collaboration could not have been any better.

"The whole transaction is a perfect example of what Austrian innovative companies are about and how successful they can be even in a growth phase."

CEELM: How about you, Philipp? What specific individuals directed your team's work, and how did you interact with them?

Philipp: Throughout all phases and work streams of the IPO process, we received excellent support and instructions from both Marinomed's top management team as well as all other team members and departments. It was impressive to experience how the relatively small management team at Marinomed was well-organized and efficient and interacted in very well-coordinated and professional manner with perfect allocation of responsibilities.

For instance, when it comes to prospectus drafting, all scientific topics were excellently covered under the lead of CSO Eva Prieschl-Grassauer, all corporate and management topics by CEO Andreas Grassauer, and all financial and account-





ing topics by CFO Pascal Schmidt. It was impressive how fast Pascal Schmidt, who was appointed CFO during the transaction, became an integral part of the management team. The entire team had a focused, constructive, and solution-oriented approach, at all times remained calm and professional even in very difficult and stressful situations throughout the process, and proved to be highly responsive and available for our requests anytime with impressively short reaction times - even late at night, on weekends, and even during the periods of their time-consuming and stressful roadshow and other non-IPO related management duties.

CEELM: How would you describe the working relationship with Herbst Kinsky on the deal?

Christoph: Honestly, the set-up with Herbst Kinsky working as issuer's counsel and us working as banks' counsel could not be any better from our point of



view. There is a professional but extremely trusted relationship between the firms' teams and in particular between Philipp Kinsky and myself, who headed the respective teams. A huge part of the legal success of the transaction is the result of this relationship as we did not waste any time discussing responsibilities but focused on getting things done. Philipp Kinsky is outstanding in this respect, has stunning know-how and experience but also finds amicable and problem-avoiding solutions all parties can live with. He is the go-to-guy for innovation companies aiming for capital markets in Austria. Therefore, I would say that irrespective of the way the communication was done there was a constant flow of smaller and larger negotiations, alignments, discussions, and development of solutions. In an IPO transaction there is usually no "final negotiation" but a constant flow of steps to be completed and this worked wonderful in this IPO matters.

Philipp: You may describe our work relationship with Weber & Co - and here especially with Christoph Moser - as a perfect match. Especially on sensitive matters like an IPO, it is crucial to have an experienced and super fit lawyer as bank's counsel on the other side of the table. It is ideal if the negotiations are focused and based on a trustful relationship. Christoph Moser is an outstanding capital

market lawyer, with immense expertise in this field. The communication was flawless, either e-mail, meetings or telcos, and Weber & Co's team was always accessible. This attainability is very important since quick decisions are indispensable. We never had been at a potential dead end point; constant communication led us to constructive negotiations, which were resolved always very quickly. In particular, the content and release of ad-hoc announcements (being always very crucial) could be arranged and agreed with highly committed Christoph Moser within very short time frames, sometimes within minutes.

"Marinomed was an enormous signal for other IPO candidates and investors that Austria is an interesting listing market."

CEELM: How would you describe the significance of the IPO to Austria?

Christoph: Personally, I believe that the IPO of Marinomed Biotech is to be seen as an icebreaker transaction not only for Austrian biotech companies aiming for an IPO and a listing on a stock exchange but also for the Austrian capital market as such. After late 2017 there was not a single IPO in the market and for 2019 it did

not look good either. Following the enormous success of the Marinomed IPO. there has now been a second attempt to go public in the market (Frequentis, which was listed in mid-May). The positive signal of the Marinomed IPO that companies can still go public in Vienna will further other issuers in conducting their ECM transactions. Erste Group Bank may also be able to establish a capital market focus for biotech companies after the successful IPO of Marinomed and I trust that other issuers will follow Marinomed's path. The whole transaction is a perfect example of what Austrian innovative companies are about and how successful they can be even in a growth phase. And finally, I may admit that for Herbst Kinsky as counsel for other issuers and for our firm as one of the few true experts on the banks' side in capital market transactions the IPO is truly an important marketing issue and will help both firms to continue playing a leading role in Austrian capital market matters.

Philipp: Since BAWAG, Marinomed was the first IPO in Austria; but it was also the first IPO in Europe in 2019; although the market environment was not supporting the transaction at all, we realized that all stake-holders, including the Austrian Financial Market Authority, Vienna Stock Exchange, the Commercial Court, and Austria-based investors were highly interested in getting this deal done. Marinomed was an enormous signal for other IPO candidates and investors that Austria is an interesting listing market. For Erste Bank the transaction was in particular important, as it showed their sales power, in particular in the DACH region and with biotech investors, a sector which Erste Bank has focused on for many years. For us it is a clear signal that we can assume senior roles in such transactions and advise on any exits of tech companies and that an IPO does not necessarily require a foreign lead counsel to execute the transaction. For Weber & Co. it is another milestone being one of the most reputable law firms in Capital Markets in Austria.

David Stuckey

AUSTRIA JULY 2019

AUSTRIAN MARKET SNAPSHOT: COURT DECISION INCREASES RISK OF MORTGAGE-BACKED LOANS



Under Austrian law, incorrect land register entries may trigger public liability. But the Austrian Supreme Court recently held that such incorrect entries only create public liability claims for of a certain group of people, thereby potentially increasing the risk management costs of mortgage-backed loans.

Background: Past Market Practice

To perfect a mortgage under Austrian law, the mortgage must be registered in the land register, a public register kept with local courts. As this registration triggers a fee of 1.2% of the secured amount, Austrian banks sometimes accept mortgages that are signed but not registered. The mortgage is then only registered if the debtor's financial situation deteriorates. To ensure the mortgage can still be registered in the first rank, the bank will agree on a negative pledge with the debtor and will check the land register before granting the loan and regularly thereafter. Banks therefore heavily rely on the land register being complete and correct. A new decision by the Austrian Supreme Court limits public liability for incorrect entries, significantly impeding this practice.

The Case

In 2000 a woman transferred real estate to her nephew with a prohibition on encumbrance and sale in favor of the nephew's son. Although corresponding land register entries were then filed and approved by the land register court, the court failed to actually register the prohibition on encumbrance and sale, while registering all other approved entries. Thirteen years later, the nephew assumed personal liability for a bank loan granted to his company. Prior to granting the loan, the bank merely checked the land register for encumbrances and relied on the status in the land register, which wrongly showed that the real estate was unencumbered.

In 2014 the bank wanted to enforce its claims by obtaining an attachment on the real estate. While the court approved the bank's lawsuit upon registering the bank's rights in the land register, it noticed that the prior prohibition on encumbrance and sale granted in 2000 had not been properly registered.

The court then corrected its past error and retroactively registered the prohibition on encumbrance and sale granted in 2000 in its original rank, *i.e.*, with priority to the bank's rights. The bank filed a public liability lawsuit for damages, arguing that it would not have granted the loan had the original prohibition on encum-



brance and sale been registered correctly.

The Court's Decision

The Austrian Supreme Court found that an erroneous non-registration of an approved land register entry, as a violation of the obligation to keep the land register accurate and complete, in principle constitutes public liability. However, even if such a provision is violated, not everyone is entitled to rely on the register's accuracy and completeness. Only a person who either already has rights registered in the land register or is aiming to constitute such rights is protected by the court's obligation to keep the register accurate and complete. As the bank did not try to register any right in the land register when the loan was disbursed, the bank was not considered a protected person, and the Austrian Supreme Court therefore denied the bank's claim for public liability.

Summary and Open Question

Following this decision, banks that only check the register for prior encumbrances but do not actually register their mortgage may no longer rely on the register's accuracy and completeness. In the future, banks will have to weigh the risk of an inaccurate or incomplete register against the costs of registering the mortgage when granting a mortgage-backed loan.

Banks may now consider registering the mortgage only for a low amount to be considered a protected person. It is not clear whether banks that do so are protected in the amount of the entire loan or only of the registered mortgage.

By Miriam Simsa, Partner and Philipp Kalser, Associate, Schoenherr Austria



CEELM: Run us through your background, and how you ended up in your current role with Knoetzl in Austria.

Emmanuel: I obtained my law degree at the University of Buenos Aires in the Argentine Republic, and I am admitted to the Bar of the City of Buenos Aires. Before starting my career in international arbitration, I worked as legal counsel at the Senate of the Argentine Republic.

For personal reasons, in 2007 I relocated to Vienna, Austria and began working at

Wolf Theiss, where I stayed until 2015. I initially started there as a legal trainee and left as Senior Associate. In January 2016, I took on the challenge to start as a Partner in Knoetzl. It was a very exciting time and a great opportunity to start something new and unique that gave me the chance

to be part of a major dispute resolution law firm – with a truly international flair – from its very beginning. From the beginning of my career in Austria, I worked with Florian Haugeneder, also a Partner in Knoetzl. We have worked together for almost 12 years now and have built a solid and effective team. Together with Patrizia Netal, also a Partner at Knoetzl, we have established a reputed arbitration practice spanning commercial, construction, international and investment arbitration.

CEELM: Was it always your goal to work in Austria?

Emmanuel: This a difficult question. I have to confess that, no. I moved to Vienna because my wife is Austrian. We meet during the Willem C. Vis International Commercial Arbitration Moot in 2006. Love is the reason I ended up in

the beautiful city of Vienna.

CEELM: Tell us briefly about your practice, and how you built it up over the years.

Emmanuel: Knoetzl is Austria's first specialized dispute resolution powerhouse dedicated to arbitration, litigation, alternative dispute resolution, business crime, and corporate crisis. Together with Florian Haugeneder and Patrizia Netal we focus on international arbitration while Bettina Knoetzl and Katrin Hanschitz focus on litigation and white-collar crime.

In the last five years, I have focused my career in construction and investment ar-

bitration. The construction practice area focuses mainly on complex engineering projects in the CEE and SEE regions (energy and infrastructure sectors) and the investment arbitration practice in Latin America as well as CEE and SEE. My Latin American background has also helped me to build a practice supporting Austrian companies doing business in Latin America.

I think one of the pivotal elements of building my practice was my interest in the actual business of my clients beyond legal aspects and cooperating closely with clients from the very beginning. This has helped to build up my own reputation and acquire the necessary skills to actively engage in business development activities. I also have always been grateful about the experience I gained by working with Florian Haugeneder and Christoph Liebscher as well as other colleagues in the previous and current law firms. Working with them has helped me to reach the position I currently have.

CEELM: How would clients describe your style?

Emmanuel: I like to think that the clients like my hands-on approach on the matters, my analytical skills, and my passion about my cases. I think that this is the best that describes me in short, and I am very humbled that it is also reflected in various legal rankings.

CEELM: There are obviously many differences between the Argentinian and Austrian judicial systems and legal markets. What idiosyncrasies or differences stand out the most?

Emmanuel: While there are differences between the legal system of Austria and the Argentine Republic, I must say that the first book that I read at the University in the Argentine Republic is "Pure Theory of Law" by the Austrian jurist Hans Kelsen (which was difficult to read since the edition I used was translated from English and not directly from German). Thus, I want to think that there is a connection between the legal education of

both countries. Moreover, both countries belong to the civil law family and display many commonalities.

In practical terms, I think that the major difference between both legal systems is how the judiciary works. I find the Austrian judiciary extremely expeditious while in Argentina court proceedings – even execution – tend to have a very long duration.

I also find it very useful that in Austria there is only one instance competent to deal with the setting aside proceedings of the arbitral awards. This is something that gives an edge to the countries that aim to be major seats of arbitration.

CEELM: How about the cultures? What differences strike you as most resonant and significant?

Emmanuel: I think one of the major cultural difference is how formal the legal profession is in Austria. I come from a country that it is more informal in the communication among lawyers. This was at the beginning something that I needed to adapt to.

In addition, punctuality is also a difference between both countries. In Argentina, time is more "flexible." A delay of 10-15 minutes is accepted. When I come back to Argentina, I am always the first one to arrive everywhere. After 12 years in Austria, in Argentina people joke that I have become more Austrian than Argentinean.

CEELM: What particular value do you think a senior expatriate lawyer in your role adds – both to a firm and to its clients?

Emmanuel: We live in a more interconnected world than ever. Companies doing business in CEE and Austria come from different countries and regions. Thus, it is important that law firms know how to handle different styles and cultures. In my view, an international team of lawyers like ours (we have lawyers with Bosnian, Serbian, Russian as well as Argentinean backgrounds) helps to build bridges to

provide for a better understanding of cultural differences.

For example, I think that companies that have a dispute in a particular region – either CEE or Latin America – find it useful to have people on the team that understand the different idiosyncrasies and markets. I can see this with my colleagues – like Selma Tiric, who comes from Bosnia and Herzegovina and studied law in Austria. She has an edge for dealing with Bosnian clients. This has also proven an advantage for me when dealing with clients with disputes in Latin America.

CEELM: Do you have any plans to move back to Argentina?

Emmanuel: Never say never but after 12 years in Austria, I find it difficult to think about coming back to Argentina. Although I miss Buenos Aires, I enjoy living in Vienna and working in CEE. This has helped me to build a career in international arbitration in a region where there are not many Latin American lawyers are based. In addition, my life center is based in Austria. One year ago, I became the father of a wonderful son.

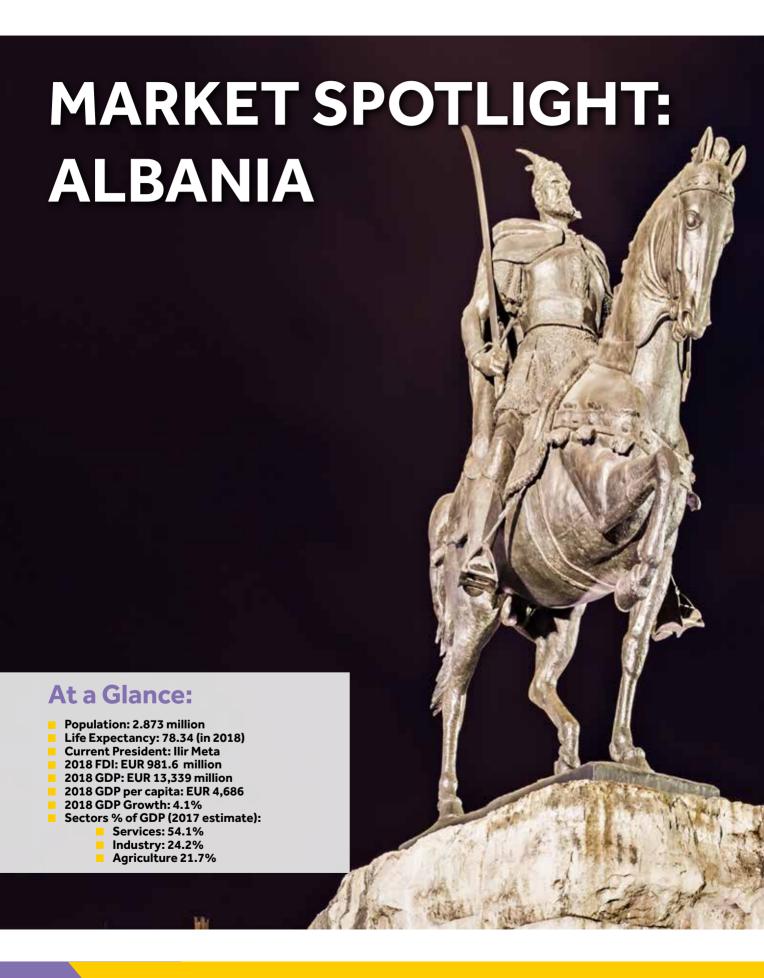
CEELM: Outside of Austria, which CEE country do you enjoy visiting the most, and why?

Emmanuel: I have to say that I am very impressed by the capital of Bosnia and Herzegovina, Sarajevo. In another life I would have been a history professor and I think that Sarajevo marked the history of the world in the 20th century. I also enjoy going to Belgrade and the Croatian coast in the summer.

CEELM: What's your favorite place to take visitors in Vienna?

Emmanuel: I think that in summer to visit the park of the Schoenbrunn palace is a must in Vienna and then have a very good local white wine while enjoying typical Austrian food in one of the many wine gardens in Grinzing.

David Stuckey



ALBANIA JULY 2019

GUEST EDITORIAL: MISMATCHED EXPECTATIONS

"Where do you see yourself in 5 or 10 years?" the Cravath partner in New York asked after fifteen or so minutes, thereby signaling that the interview was coming to an end, expecting to hear the standard reply emphasizing the applicant's desire to work hard if offered the position. "Home," I replied. "In Albania."

Almost twenty years have passed since that interview, which lasted for another two hours. I spent almost a decade working at Cravath learning from the best legal minds in the corporate world. However, when my first daughter became school age, the time came to fulfill my homecoming vision. Many friends, particularly Albanian ones, were perplexed with my forewarned move. All asked: "Coming from this world" – in their eyes, one of glamour and wealth – "what do you expect to find back home?!"

I was not someone who had lost touch with reality and become overcome with nostalgia. I fully knew where I was returning – in the words of my Montenegrin colleague Vladimir Radonjic from a previous CEELM editorial – in a region where "nothing can be taken for granted," without "fully effective democracies," and where "enforcing the rule of law remains problematic...." I expected all of that.

Still, I believed that as a developing country with ambitions to join the EU, blessed with natural resources, a beautiful coastline, and a young and educated population, Albania would become an attractive option for FDI – investors would want to get in on the cheap and profit from Albania's economic rise and EU integration. I hoped that a healthy portion of that inflow of transactions would go to professionals who "spoke their language." I also assumed that even Albanian businessmen would be eager to learn best practices and grow responsibly so they could compete as equals with their EU counterparts. I expected that I would find many like-minded professionals who would be excited to build a future here.

It has now been five years since I founded my legal and business consulting firm in Tirana. However, five years in, there is a considerable gap between my expectations and the reality. The influx of FDI in Albania has hovered around EUR 180 million a year over the last 15 years, driven primarily by a small number of large infrastructure projects. American investment is almost non-existent. There are droves of opportunistic non-Western potential investors who are keen to take first and second (free) Q&A meetings, but then disappear. The number of local businessmen who are not surprised by the number of pages in a M&A contract is very limited – given the history of whimsical judicial processes so easily influenced by outside factors, they continue

to be content with short-term solutions based on personal connections rather than necessary and sophisticated legal mechanisms. The bulk of business is still government-dependent – and both before and after

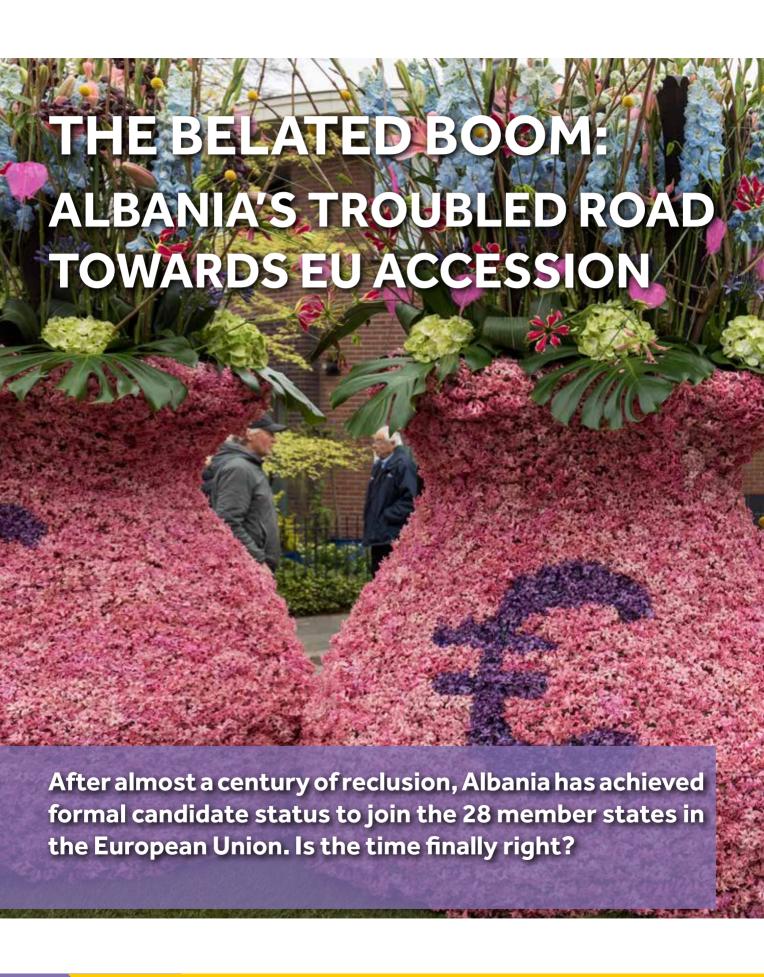


elections the Albanian business world almost stands still. Furthermore, while our firm has grown to a healthy number of well-credentialed professionals, finding top talent that is invested in a future in Albania remains challenging. Rewarding these lawyers in a way that is comparable with law firms in the West is impossible - particularly given that clients expect New York-quality product for heavily discounted fees, even by local standards.

I know that "mismatched expectations" is a theme that runs across CEE, beyond my experience with the Albanian legal market. Dissatisfied with Albania's political class, perceived corruption, a weakening educational system, and the continued monopolization of the economy, and faced with the EU's reluctance to embrace new member countries (expressed most recently through the moving goal posts of initiating accession talks and the EU-sponsored experimentation with Albania's legal reform), a growing number of Albanians believe that emigration is the answer.

Yet, there undeniably has been progress. The absolute majority of those who want to emigrate are undoubtedly better off today than they were five, ten, or twenty years ago, and Albania's issues are by no means unique in the region or beyond. However, Albanians' expectations of where the country should have been almost 30 years after the overthrow of communism, justifiably or not, are too mismatched with the reality they perceive, regardless of statistics, EU commission reports, economic forecasts, or even the salaries they make. In today's younger generations, patience seems no longer to be a virtue, which, I am (irrationally) hoping that will turn out to be a good thing. For my part, I am using the gap as fuel to keep plugging in and working towards our stated goal: to become the most trusted and respected firm in Albania, recognized by our clients for delivering excellence, by our competitors as the standard setter, and by aspiring young professionals as the best place to develop their talents.

> Rezart Spahia, Managing Partner, Frost & Fire Consulting



THE BELATED BOOM JULY 2019



Political Crisis at a Time of Opportunity

The desire to join the EU, it appears, is the rare sentiment that everyone in Albania seem to share. "If there is one thing common in Albania, it is its path to the EU that everybody agrees on – the government, the opposition, and civil society," says Frost & Fire Consulting Co-Managing Partner Alfred Rushai. "The path to Europe is the national goal for everybody."

Still, despite the across-the-board support for EU accession, Albania finds itself in the midst of high tensions that jeopardize the country's progress. Since February 2019, the country has found itself mired in political crisis, as the opposition, led by the Democratic Party, has withdrawn from Parliament and demanded the resignation of current Prime Minister Edi Rama, whose election in 2017 generated wide-spread accusations of fraud and corruption. Tensions have only increased since, with widespread protests and declarations by members of the Democratic Party that they will refuse to participate in any elections, including the municipal elections originally scheduled for June 30, 2019, until their demands are met.

In response, Albanian President Ilir Meta canceled the June 30 elections, purportedly to decrease tension in the country and make sure the process towards EU integration was kept on track. Meta's decision, however, was not welcomed in Parliament, particularly by the governing Socialist party, which vowed to remove the President for what they claimed was an unconstitutional act, which, Rama claimed, "undermine[d] Albania's democracy." Indeed, on June 24, 2019, the Electoral College - the highest judicial body in Albania on electoral matters unanimously ruled against the president's decision and ruled that the local elections should proceed. Anti-government violence increased as a result, with opposition supporters for the first time targeting the elections specifically, breaking into nearly a number of electoral facilities and destroying election materials, leading to clashes with police and multiple arrests.

In addition to the immediate crisis, a number of experts express frustration about the effect of the sturm-und-drang on the country's economy. "It is very easy in such economically hard times to dissuade investors from taking a business risk in this country," says Wolf Theiss Partner Sokol Nako, "and that level of political conflict does not help. Everybody prays for a more streamlined political debate and higher standards of governance," he says, "thus, any improvement in the government could ease tensions and indirectly be much more helpful to business."

"The crisis might cause a slow-down in some legislative reforms," says Deloitte Legal Senior Manager Sabina Lalaj, speaking before the Electoral College's decision. Lalaj emphasizes that she prefers dialogue to drastic measures, and says that, one way or another, she hopes that things will stabilize by September.

The internal political crisis isn't the only major problem Albania is facing at the moment. Although the European Commission recommended in May that accession talks with both Albania and North Macedonia begin as soon as possible, saying the two countries have "delivered on reforms," in mid-June the EU postponed its decision about whether to open those accession negotiations, promising only that "the council will revert to the issue with a view to reaching a clear and substantive decision as soon as possible and no later than October 2019."

Corruption and Lack of Transparency Continue to Limit Growth

Earlier this year, in its report about Albania, the European Commission reported that the country had made "moderate progress" in such key areas as the judiciary, public administration, and economy, but noted that corruption is "prevalent in many areas and remains an issue of concern." In fact, the problem may be getting worse, not better. Transparency International's 2018 Corruption Perception

tions Index ranks Albania 99th among the 180 countries and territories included in the report, down from 83rd in 2016. According to Transparency International, the increased corruption in the country is largely the result of a political situation which limits enactments of necessary reforms.

"If there is one thing common in Albania, it is its path to the EU that everybody agrees on – the government, the opposition, and civil society. The path to Europe is the national goal for everybody."

Indeed, with corruption rampant across the political spectrum, many express cynicism about whether or not the jockeying for political power has much to do with the ultimate direction of the country in the first place. "There is not much difference between the colors of the government," Shpati Hoxha, Partner at Hoxha, Memi & Hoxha says, sighing. "The major issue is corruption. Problems in Albania are always the same, irrespective of the government."

And Hoxha says that the steps the country has taken to tackle corruption have been mostly ineffective. "There are changes on the way, some things have been done, but the end result is the same – if you do not have political connections or are not able to somehow build a favorable relationship with the government, you will not be able to succeed." What's more, he says, "it is especially difficult for foreign investors to compete in the corrupt environment." Hence, he believes, "only those businesses which are able to access the corrupt mechanism do and will succeed in business." As a result, he suggests that Albania's claims to be addressing corruption amount to window-dressing. "I do not think anybody is making any honest efforts," he says.

Frost & Fire's Rushai agrees that corruption remains a major problem, but he

insists that it is hardly the only challenge the country is facing, citing also a lack of transparency that affects how the market functions for foreign and local investors and how public procurement procedures and public competitions operate, as well as hampering the legislative process and the implementation of laws and regulations. The two problems are, of course, related. "The lack of transparency fuels corruption," Rushai says, and while he says most of the time there are no issues with laws themselves, their selective implementation is a real problem.

And there's no silver bullet, apparently. "I do not think that a single piece of law can make a difference," Rushai says. "It needs to be a whole initiative to significantly change the climate of doing business here." He adds that the problem is only aggravated by a lack of accountability for public officials. "All of these things result in a clear deformation of the market."

Lalaj reports that Albania's tax system is a major obstacle as well. "We need to better educate and improve our tax administration and give more flexibility and more access to both foreign and local investments," she says. She describes the current system as based on "old traditions and bureaucracy," and she suggests that better communication with tax authorities and an improved understanding by those authorities of the needs of the business community would go a long way.

Hoxha says, the market has been experiencing a slow-down in foreign investment and significant divestments, such as Societe Generale being sold to OTP in April 2019 and Deutsche Telekom leaving the market in January 2019. Hoxha ties the slow-down in large part to changes in the fiscal system and the overall increase of tax rates.

Indeed, Kalo & Associates Executive Partner Aigest Milo reports that, since the ruling party came to power, corporate income tax rates have been increased from 10% to 15%, and a progressive tax on employment has been introduced. The problem was not helped, he says, by



Aigest Milo





the government's decision to conduct an ineffective audit of small, medium, and large companies that stressed the economy.

In addition, Milo says, one of the objectives of the newly-formed government back in 2013 was to repay the VAT that was due to businesses. "It was EUR 250 million at that time, which they reimbursed, but now the amount is nearly the same," he says, "meaning along the road this government approach has failed and

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we are back at square one."

Of course, the size of the market is also a factor. Milo says that the opportunities for potential return for foreign investors are limited. "What investors put into this market and what they get in return is not what is expected," he explains.

Not All Doom and Gloom

But there's certainly been *some* progress, and Rushai reports that even the EU accession process itself is positively affecting the nation. "We have objectives to reach in order to achieve certain milestones," he says, and adds, "this is good for business, the market, democracy, for everything, as we are checked by independent supervisors to keep up."

On its website, the World Bank reports that Albania has achieved "remarkable economic progress during the past three decades" transforming itself in the process "from one of the poorest countries in Europe into a middle-income nation." For its part, on its website, the European Commission points out that, at least before the global financial crisis hit, Albania was "one of the fastest-growing economies in Europe."

And, despite all the potholes and difficulties with corruption, the government is often credited with being pro-business. Major initiatives include the Devoll Hydropower project (consisting of two hydropower plants being built in the Albanian valley of Devoll, which will produce 729 GWh annually, increasing Albanian electricity production by almost 17 percent), and the Trans-Adriatic Pipeline, which will transport natural gas from Greece, through Albania, under the Adriatic, to Italy and then on to Western Europe.

In the past several years, Albania's energy sector also became attractive to foreign investors, Milo says. In 2017 Albania adopted a new Act on Promotion of the Use of Energy from Renewable Sources. The new law, which is harmonized with EU Directives, made conditions much clear-

er, he reports, as the government seeks to capitalize on its remarkably warm and sunny climate and extensive coastline. However, there is a general concern for the future of FDI, he admits, as both the Trans-Adriatic Pipeline and the Devoll project will be concluded next year.

"There are changes on the way, some things have been done, but the end result is the same — if you do not have political connections or are not able to somehow build a favorable relationship with the government, you will not be able to succeed."

Lalai also points to tourism as a significant source of investment and cites several important incentives in the sector, such as the introduction of new tax policies for hotels and resorts (including reducing VAT from 20% to 6% and exempting profit tax for ten years) designed to lure more four and five-star hotel chains to the country. Hilton - through Hilton Garden - already has a hotel in the market, while Marriott International and Hyatt Hotels Corporation have signed agreement for hotels in Tirana. Lalaj reports that several other hotels are expressing interest in the country as well. In fact, construction projects are prevalent in Albania, and according to the Institute of the Statistics in Albania, Industry and Construction constituted 20% of the country's GDP in 2017.

The country's efforts to reform its property registration system is also expected to make things easier for foreign investors. In the past Albania's system was divided into three overlapping and often ineffective parts: a property registration office, a legalization agency, and a restitution agency responsible for returning property taken by the state during the communist era to its former owners. The move in April 2019 to combine them into one e-cadastral office is widely seen as an improvement. "It is an important agency for businesses," Milo says, "we will have





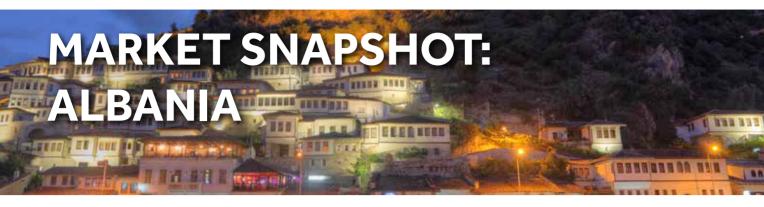
one register for all properties and a much clear property regime, which, it should be emphasized, is one of the major problems for foreign investors."

A Clear Perspective

Despite its many problems, many claim they remain positive about the country's overall progress. As Nako puts it, "I believe that a clear perspective really would soften the image that Albania has in the eyes of investors and would provide the synergies for everyone to look at us more favorably." He says that the current situation reminds him of Bulgaria and Romania in their early 2000s pre-accession stages. "Once the perspective became clear, you could see that with investor interest and cross-border investment becoming higher and with the support of EU funds and programs, their economies boomed."

Maybe Albania's boom is coming?

Mayya Kelova



NEW DRAFT "ON THE FISCAL REGIME FOR PETROLEUM OPERATIONS" LAW



The fiscal aspects of the hydrocarbon sector in Albania will be soon governed by a new law. The new draft "On the Fiscal Regime for Petroleum Operations" law (the "New Draft Law") was initially published in the Electronic Register of Public Announcement and Consultations on April 4, 2019 and has been circulated

for comment among stakeholders, chambers of commerce, and experts' associations in Albania.

The new law governing the fiscal regime in the petroleum operations sector was drafted following a long-standing demand by the Albanian petroleum sector, driven by the fact that, despite many amendments, the existing legislation is outdated. Indeed, the current law – law No. 7811, "On the approval of the Decree no.782, dated February 22, 1994 'On the fiscal system in the petroleum sector exploration and production," as amended – dates back to April 12, 1994.

Through this new piece of legislation, the lawmaker aims to create a legal instrument to prevail over the provisions of petroleum agreements and to safeguard the interests of the Albanian Government vis-a-vis the private operators of the sector – and at the same time to assure the collection of a higher amount of taxes.

While drafting the New Draft Law the lawmaker has taken a very conservative approach toward the operators in the petroleum sector, and the unsophisticated legislative technique increases the ambiguity and insecurity for the actual operators and potential future investors.

The New Draft Law raises several issues, two of which require the immediate attention of the lawmaker: (i) the prevailing effects of existing petroleum agreements in the sector; and (ii) the extension of those effects on current subcontractors operating in the petroleum sector.

Notwithstanding the intention of the lawmaker to have a prevailing law, due to the impossibility of overruling effective petroleum agreements, the New Draft Law provides that petroleum agreements effective prior to the enacting of the new law will prevail over its provisions.



However, the New Draft Law

emphasizes that any new amendment to current petroleum agreements must be done in accordance with the new law's provisions. The aim of this provision is to eliminate the possibility of petroleum operators obtaining any advantage/benefit in their petroleum agreements by deviating from the general rules provided in the New Draft Law.

This approach towards future amendments of petroleum agreements once again reflects the intention of the lawmaker to induce entities conducting petroleum activity based on current petroleum agreements to comply with the provisions of the New Draft Law.

The second implication requiring immediate attention is the obligation introduced in the New Draft Law that: "in order to prevent the avoidance of the fiscal regime, this Law may be extended to apply to persons conducting petroleum operations on behalf of other persons (referred to as 'subcontractors')."

This provision brings major uncertainty, as it is unclear if this extension would only apply in cases of abuse with the tax legislation or could be interpreted by the tax authorities as applying to all subcontractors. In the second scenario, subcontractors will be liable for a profit tax rate of 50%, which would have a significant economic impact on the petroleum operations market.

As mentioned previously, from a legislative technique perspective the New Draft Law provides overcomplicated provisions, unclear definitions, and completely new terminology for the sector, compared to the terminology used previously MARKET SNAPSHOT JULY 2019

in petroleum agreements and the petroleum sector.

If the New Draft Law is approved or implemented as it is, it will negatively affect the market, and it will lead to debate, lack of transparency, and compliance-related issues. Therefore, a through revision of the New Draft Law, based on the comments of the experts and groups of interest, would be very beneficiary to the sector.

By Sabina Lalaj, Head of Practice in Albania and Kosovo, and Erlind Kodhelaj, Senior Managing Associate,
Deloitte Legal

ELECTRIC ENERGY IN ALBANIA



During the last decade, Albania has undertaken several initiatives to liberalize the electric energy sector and increase local generation capacities. Such measures have created a lively market, especially in the renewal energy segment.

The internal market is under continuous improvement,

both technically and commercially, and the renewable energy sector in Albania offers good investment opportunities, with a high degree of legal security for foreign investments.

Electric Energy Framework

In 2015, the Albanian Parliament passed a new law reforming the electric energy sector that is designed to create a competitive and liberalized energy market by establishing the Albanian Power Exchange as a day-ahead and energy balancing market.

In addition, in 2017 the Parliament passed a new law promoting the use of energy from renewable sources (the "Renewable Energy Law").

State of Play

With the exception of transmission and distribution activities, the sector is liberalized and a good number of local and foreign investors are active in energy generation and trade. However, as the majority of private energy producers currently enjoy feed-in tariff incentives, a degree of regulation is applicable to energy generation.

The supply of electric energy is also in principle liberalized, but with the exception of high demand customers (consuming more than 50 million kWh/pa) or those connected above 0.4 kV (with few exceptions) who must access the liberalized market, in practice households and other consumers continue

to be supplied by the state-owned universal service supplier.

Domestic generation currently consists of almost 100% hydropower generation. A thermal pant of 98 MW is owned by the state-owned energy producer, but it is not operational.

Renewable Energy and Incentives

To reduce its dependency from imports and meet its UN-FCCC commitments, in 2018 the Albanian Government approved the National Action Plan for Renewable Energy 2018-2020, which provides for the increase of renewable energy generation capacities by 798 MW (600 MW in hydro power, 70 MW in wind power, 120 MW in solar power, and 8 MW in waste to energy units). The Renewable Energy Law offers priority access to the grid, simplified grid connection requirements, issuance of transferrable certificate of origin, financial incentives, and a temporary exemption from the energy balancing regime (until December 31, 2022, or until the full establishment of a balancing marketplace, whichever occurs first).

The current financial support mechanism available to renewable energy producers is the feed-in tariff system, consisting of a fixed price for kWh (as approved by the energy regulator (ERE) on an annual basis of electric energy injected in the grid (currently approximately EUR 68/MWh)). In addition, ERE has approved premium tariffs to incentive small wind and solar plants of EUR 76/MWh for wind with up to 3 MW capacity and EUR 100/MWh for solar with 2 MW capacity (these tariffs are currently being updated).

The feed-in tariff mechanism will be available for a period of 15 years to renewable energy producers that start operations before December 31, 2020. Renewable energy producers that start operations after this date will no longer benefit from the feed-in tariff mechanism (with the exception of small wind and solar plants, which will continue to enjoy the feed-in tariff mechanism), but will be able to apply for the new financial support mechanism of the Contract for Difference (CdF).

Under the CdF mechanism, which will be accessible through competitive procedures, renewable energy producers will receive a fee equal to the negative difference between the price offered during the competitive procedure and the price they are able to achieve in the open market for the sale of the energy they generate

Renewable energy producers will be able to benefit from the CdF mechanism for a 15-year period, or until they have achieved the return on investment, minus other eventual received financial support.

By Shpati Hoxha, Partner, Hoxha, Memi & Hoxha



The subject of Experts Review this time around is Pharma and Life Sciences, with a significant number of authors choosing to focus particularly on the laws and legal regimes relating to medical marijuana.

Life Sciences being the theme, the articles are presented by average life expectancy per contributing country, as reported by the CIA World Factbook in 2015. So the article from Austria, where the average person lives to the ripe old age of 81, comes first, while the article from Russia, where the average person lives between 70 and 71 years, comes last.



AUSTRIA

Cannabidiol: Is CBO in Medicinal Products, Novel Food, and Cosmetics Welcomed or Simply "The Devil" If Used at All?





The Supreme Court of Cassation in Italy has recently rendered a decision that products containing Cannabidiol (CBD) shall be prohibited from being marketed on the Italian market, even if they contain less than 0.2% of the psychoactive substance Tetrahydrocannabinol (THC). The sale of such products had previously

been permitted based on an amendment to the law regulating hemp production that removed the requirement to obtain a permit for "cannabis light." This led to a "cannabis light boom." The change was triggered based on the opinion of the Highest Italian Sanitary Council that even such "cannabis light" products could conceivably endanger human health. Following the Supreme Court of Cassation's ruling, only products specified as medicinal products or certain agricultural varieties may be sold.

Similarly, in December 2018 the Austrian Federal Ministry of Labor, Social Affairs, Health and Consumer Protection (Bundesministerium fuer Arbeit, Soziales, Gesundheit und Konsumentenschutz) issued a binding order heavily restricting the use of CBD in cosmetics, food, and food-supplements, and as liquids for electronic cigarettes. And the guidelines of the German Federal Office of Consumer Protection and Food Safety (Bundesamt fuer Verbraucherschutz und Lebensmittelsicherheit) take a similar path with respect to how CBD should be classified in the various product categories. Both the Germans and the Austrians also took the fact that products containing THC often exceed the permissible threshold into account. All three countries have heavily limited the use of CBD in products which can be freely marketed without specific authorization (unlike, for instance, medicinal products).

Cannabis sativa undoubtedly constitutes a narcotic substance

under the Single Convention on Narcotic Drugs and has a pharmacological effect - including, among other things, an anti-psychotic, neuroprotective, or anti-inflammatory effect. This means that products containing cannabis sativa can only legally be marketed if they have obtained a marketing authorization in accordance with the Human Use Directive if the THC content is above 0.2 % (in Germany) or 0.3 % (in Austria). Products containing CBD as an active substance are already approved as medicinal products – in Germany, for instance, such products can only be obtained via a prescription. Not only can the pharmacological properties trigger the application of the Human Use Directive, but also the presentation of the product per se. If the product is advertised using diseases related claims, the product would qualify as a medicinal product even if the THC content is below 0.2%. Austrian authorities are increasingly checking homepages advertising CBD products.

According to the EU Novel food catalogue, synthetically obtained Cannabinoids are considered novel food, thus require authorization in accordance with the Novel Food Regulation. Even if extracted in a natural way, CBD is classified as a novel food, as it is when added to traditional hempseed products, under the wording "this applies to both the extracts themselves and any products to which they are added as an ingredient." Therefore, only traditional food such as hempseeds, hempseed-oil, hempseed-flour, or fat free hempseed proteins can be legally marketed within the European Union. The use of CBO in veterinary food supplement products is also not permissible for the German authorities, which also pursue companies sending such products via mail order to Germany.

For CBD in cosmetics there are some differences – and the Austrian Ministry strictly prohibits use in cosmetics altogether simply for the listing of cannabis in the Single Convention.

In various countries CBD is used as a liquid for electronic cigarettes as well. The Austrian Ministry states that such liquids are not permissible at all (even if the THC content is under 0.3%) out of a concern that consumers could be misled into believing that CBD liquids have a positive health effect due to the pharmacological effects. The Austrian Tobacco and Non-Smoker Protection Act does not allow any claims going into this direction. This opinion of the Ministry is triggered more by the political position that CBD products should not be on the Austrian market at all.

What can be derived from the Austrian, German, and Italian approaches? These three countries currently consider CBD products as the devil and are of the opinion that products containing CBD should not be marketed for human/veterinary consumption until scientifically valid data is available, either gained during a clinical trial or during an evaluation in accordance with the Novel Food Regulation supporting the safe use of such products.

Karina Hellbert, Head of Life Sciences / Pharmaceutical Law, Polak & Partner Rechtsanwalte

CZECH REPUBLIC

Ongoing Struggle for Access to Medical Cannabis



Ukraine The Czech Republic was one of the first countries in Europe to allow the use of cannabis for medical purposes. This was achieved in 2013 by means of an amendment to the Act on Pharmaceuticals, which was subsequently implemented by the "Cannabis Regulation." Despite this, access to medical cannabis

still remains difficult for many patients.

Prescribing Medical Cannabis

Qualitative requirements: The term "medical cannabis" refers to the dried female flowers of the plant Cannabis sativa L. or Cannabis indica L., with levels of THC (tetrahydrocannabinol) and CBD (cannabidiol) within the ranges set out in the Cannabis Regulation. The ranges are wide – from 0.3 percent to 21.0 percent for THC and from 0.1 percent to 19.0 percent for CBD.

Indications: Medical cannabis is used as an auxiliary treatment to alleviate symptoms accompanying serious illnesses. Medical cannabis can only be prescribed by doctors with the appropriate specialization and only for the health indications listed in the Cannabis Regulation. For example, specialists in neurology and geriatrics are allowed to prescribe medical cannabis for a wide range of health conditions, including spasticity and pain associated with multiple sclerosis. In order to make information on prescribing doctors and their specializations accessible to patients, the State Agency for Medical Cannabis publishes a list of doctors on its website.

Quantity Limit: The total amount of medical cannabis that can be prescribed to a patient was originally limited to 30 grams per month. This was increased to 180 grams per month. Medical cannabis can only be prescribed by means of an electronic prescription system, known as the "register of restricted medical products," which can be accessed by doctors and pharmacists. Pharmacists dispensing medical cannabis must check whether or not the patient has already reached the monthly limit.

Possession

Although growing and possessing cannabis is generally forbidden, possessing medical cannabis under prescription is an exception. The police have the right to demand the patient's ID card and to check the register to verify the amount of medical cannabis already dispensed to the patient. Possessing more than the prescribed limit could be considered a minor offence or a more serious crime, depending on the amount.

Barriers to Access

For the first two years after passage of the medical cannabis law, patients were blocked from obtaining cannabis because there was no electronic register of restricted medical products; it only became operational in 2015. Then, due to difficulties in the public tendering process for suppliers of cannabis to the Czech market, there was a



shortfall of cannabis in pharmacies. Currently, price remains the major barrier to patients wanting access to medical cannabis.

Generally, public health insurance does not cover prescriptions of medical cannabis. The law provides for an exceptional reimbursement in special situations, where the medical product in question is the only suitable treatment for the patient's condition. Considering these stringent conditions, it comes as no surprise that insurance companies are strongly opposed to reimbursing the cost of medical cannabis. In one noteworthy case, after considerable media coverage and repeated litigation, including a complaint to the Constitutional Court, the General Health Insurance Company (the largest, state-owned insurer) agreed to pay the cost of the medical cannabis prescribed to the patient, who suffered from multiple sclerosis.

Proposed Changes to Reimbursement

A bill introducing insurance coverage of medical cannabis is currently under debate in Parliament. According to the bill, insurance would cover 90 percent of the price of up to 30 grams of medical cannabis per month. If approved by the insurance company's doctor, this could be increased to 180 grams per month (*i.e.*, the total quantity limit). This approval requirement may represent a barrier to access for patients with severe conditions who need larger amounts of cannabis.

The bill also introduces a new duty on doctors prescribing cannabis, requiring them to inform the regulator about the method and results of treatment for each patient receiving a prescription. This duty could be burdensome for doctors and may potentially discourage them from prescribing it.

Conclusion

Even though prescription of medical cannabis has been permitted for the past six years, the number of patients using it remains low. Currently, this can primarily be attributed to the high price of medical cannabis and lack of insurance coverage, which particularly affects patients with severe conditions needing larger amounts of cannabis. Even if passed, the new bill introducing insurance reimbursement of medical cannabis will not remove the barrier for such patients.

Monika Maskova, Partner, and Michal Rehorek, Associate,
PRK Partners

SLOVENIA

Trends in Liability for Defective Products Involving Vaccines





Pharmaceutical products have been in the spotlight of the Council of the European Union's Product Liability Directive since its adoption in 1985. Despite the amount of time that has passed, some legal uncertainties remain that strike directly at the notion of defectiveness, as well as the causal link between the defect and

the damage (which proved to be even more important in the case of pharmaceutical products). Establishing such causal link in cases involving vaccines is notoriously difficult, especially from the perspective of a lay consumer. This has led some EU member states, such as France, to introduce case law aimed at facilitating the burden of proof in specific sectors.

The European Court of Justice has, for example in the Novo Nordisk Pharma GmbH v. S case, limited such potential circumventions of the Product Liability Directive by allowing only those alternative systems that existed prior to the Product Liability Directive. Such a distinction seems to be especially important for Slovenia and Croatia, as both introduced product liability into their legal systems even before the introduction of the Product Liability Directive.

National legislators in these countries, however, did not take the additional step of facilitating the burden of proof, which, pursuant to the Product Liability Directive, lies with the consumer. The European Court of Justice held in several landmark cases that the nature of the Product Liability Directive is in full harmonization with national legal systems, preventing the shift of the burden of proof away from the consumer to the producer of a specific product.

One relatively recent decision by the European Court of Justice, Boston Scientific Medizintechnik GmbH v. AOK Sachsen-Anhalt, has led some commentators to conclude that the Court is apparently relativizing its strict position regarding the burden of proof by widening the notion of the defect. Pursuant to the Product Liability Directive, a product is defective when it does not provide the degree of safety which a person is entitled to expect. This has generally been interpreted to mean that the plaintiff must prove that a specific product had a defect, which caused damage. In the Boston Scientific Medizintechnik case, however, the Court held that, if an entire series of products suffers from a defect that increases the risk of damage, there is no need to establish a defect in each individual product pertaining to the same batch. Such reasoning has important consequences for pharmaceutical products as well, since they are generally produced in batches.

However, the most recent case law of the European Court of Justice from 2017 does not support the trend of facilitating the consumer's burden of proof. In this case, a person developed symptoms of multiple sclerosis shortly after being vaccinated against hepatitis B. Following his death in 2011, members of his family brought an action for damages against Sanofi Pasteur, which was the manufacturer of the vaccine. Following the initial success of the plaintiffs, and the subsequent overturning of the decision by an appellate court, the plaintiffs relied on the case law of the French Court of Cassation, according to which the proof of a causal link in the case of pharmaceutical products between the defect and the damage can be derived from serious, specific, and consistent presumptions.

The question for the European Court of Justice was, therefore, whether such presumptions under national case law for pharmaceutical products are in line with the Product Liability Directive's burden of proof, which lies with the consumer. Importantly, the court observed that even if the ambition of the Product Liability Directive is full harmonization, the directive itself does not regulate all matters. For example, procedural aspects, including evidentiary rules, are governed by national legislation, which is bound by the principle of effectiveness. Therefore, national legal systems cannot undermine the total effectiveness of the system of liability introduced by the Product Liability Directive.

The court held that only rebuttable presumptions which are based on factual evidence constitute serious, specific, and consistent evidence that there is a defect and a causal link between the defect and the disease. Importantly, the Product Liability Directive precludes evidentiary rules according to which a causal link is proved if medical research neither establishes nor rules out the existence of such a link, and only certain predetermined causation-related factual evidence is presented.

Recent case law in product liability confirms that plaintiffs cannot succeed by relying on national evidentiary rules that effectively result in the reversal of the burden of proof. Considering strong objections from the professional public, it remains to be seen whether the anticipated reform of the Product Liability Directive will bring any changes to these issues.

Igor Angelovski, Partner / Independent Attorney at Law in cooperation with Karanovic & Partners

POLAND

Poland Leads the New Rise in CEE Life Sciences





It is a good time for the CEE region, and for Poland. In September 2018 Poland became the first country in CEE to be ranked as a "developed market" in the FTSE Russell index. And the Polish Life Sciences market, which had previously been driven by a transition economy dogma, has made a leap from a purely generic market to a more innovative one. A few re-

cent developments may allow Poland to become a leader in the CEE Life Sciences industry.

Economic Trends

Traditionally the Life Sciences market in Poland (as elsewhere in CEE) has consisted of generic and branded generic manufacturers. Poland has the biggest share of the primary pharmaceutical market in CEE, with a steadily-growing number of pharmaceutical and medical device companies. Health-related industries are among the most rapidly-expanding innovation sectors in Poland. R&D provides for the largest share of innovation expenditure, followed by investment in capital goods with embedded technology. The Polish Life Sciences industry is supported by state funding, in particular by the European Commission and Poland's National Center for Research and Development. According to a recent report by the Polish Patent Office, the Polish Life Sciences industry (in particular health tech) has grown steadily since Poland's accession to the EU and now includes around 100 large and small business entities. Since 2010 companies in Poland have accounted for 2.7% of all new healthcare technology in the EU.

Patent Trends

Recently, EU investment in Poland has contributed to greater domestic innovation and has strengthened EU ties to the domestic R&D scene. Furthermore, the growing awareness of IP issues is increasing the number of inventions registered at the Patent Office.

According to the Patent Office's report on the scale and intensity

of patenting activity, Polish health sector entities filed 34,639 applications for worldwide IP rights (patent and utility model applications) between 2006 and 2015, including 3,193 patent applications and 270 utility model applications, of which 1,656 (48%) were in pharma and 1,807 (52%) were in med-tech. The share of



healthcare applications in Poland increased by 6% to 8% yearly since 2010. The top 14 most valuable applications were filed in the health sector (both pharma and med-tech). Most Polish Life Sciences companies file their patent applications in Poland (76%). Nearly half of all patent applications were filed jointly with other applicants. Also, most patent applications were filed for non-biological preparations (42%) and new chemical compounds (31%). The key specializations in the field of medtech were in the fields of diagnosis & surgery (34%) as well as stents, orthopaedic, nursing or contraceptive devices, treatment or protection of eyes or ears, bandages, dressings, or absorbent pads (18%). There were 534 patent applications filed with the European Patent Office by Polish entitles last year alone, and this trend is increasing.

Finally, it is worth noting that top foreign Life Sciences giants patent in Poland as well. More than 50% of foreign patents originated from Germany, followed by the US, France, Switzerland, Italy, the Netherlands, and Japan.

Legal Trends

A trickle of patent and regulatory clashes has been flowing through Poland's courts, with a rising number of confrontations between foreign pharmaceutical titans and local rising stars. With a total of 13,432 healthcare-related national and PCT applications and validations of European patents, Poland is the leader in the CEE region.

The hot news is that the Polish Ministry of Justice has initiated public discussions about specialized IP courts in Poland (primarily for trademarks and patents), which may facilitate dispute resolution in the Life Sciences sector and thereby increase the effectiveness of IP protection for Life Sciences companies. Furthermore, in mid-May of this year the Polish Ministry of Entrepreneurship and Technology launched another public debate on the Unified Patent Court system. The Polish decision to opt out of the Unified Patent Court means self-preservation for the country's patent scene. Moreover, Poland will keep its hands on the local patent policy and no Life Sciences company can omit Poland from its strategy when launching a new patent-related product into the market. Further developments in this area are eagerly awaited!

Przemyslaw Walasek, Partner, and Agnieszka Sztoldman, Head of Life Sciences and Pharma, Taylor Wessing Poland

SLOVAKIA

Medical Malpractice in Slovakia





Medical professionals in Slovakia must adhere to current professional standards. Failure to do so may result in administrative, civil, or criminal liability. Patients have several options how to proceed in the event of alleged medical malpractice.

The least frequent – and least effective – of the available options is to file a complaint directly to the healthcare provider. This makes sense only in cases involving large providers such as hospitals, and not in cases involving a general practitioner or specialist practice operated by a sole practitioner.

In most cases, the patient files a complaint to the Healthcare Surveillance Authority (HCSA), which is a specialized public administrative body empowered to investigate whether healthcare services were delivered properly. The HCSA's review involves a board of consulting physicians and the scope of the review is limited to medical records only. No other facts are taken into account. The patient is not a party to HCSA proceedings and is informed only whether or not healthcare was provided in accordance with currently established standards. In the majority of cases, patient complaints are unfounded. In 2017 alone, more than 80% of patient complaints were rejected. Data for other years shows approximately the same proportion of unfounded complaints.

If malpractice is found, the HSCA initiates administrative proceedings to impose sanctions against the healthcare provider. These sanctions can include fines (up to EUR 3,319 for natural persons and EUR 9,958 for legal entities) and a ban on providing healthcare services for up to one year (in the case of a legal entity, the ban is imposed on an expert representative of the legal entity who is a medical professional). The HCSA may also impose measures to remove any identified deficiencies or

oblige the sanctioned healthcare provider to adopt measures to remove such deficiencies. After an investigation is closed, the HCSA may reopen the case, even repeatedly, if new facts are available and such facts could have an impact on the investigation's outcome. The statutory limit for reopening a closed case is one year.

In recent years there has been a discernible increase in the number of criminal complaints for alleged medical malpractice. The rationale behind this trend is that, unlike in an HCSA proceeding, in a criminal proceeding the patient has the status of a damaged party. Under the Slovak Criminal Procedure Code, the status of a damaged party is strong and includes, *inter alia*, the right to propose or submit evidence, the right of access to the case file, and the right to compensation. Another factor is that while decisions in criminal cases of alleged malpractice rely on expert opinions, the costs of these expert opinions are borne by the state, which makes this option economically feasible and attractive for patients.

In most cases, criminal proceedings are also significantly faster than civil proceedings. The HCSA itself usually lodges criminal complaints in the most blatant cases of malpractice. Additionally, under certain circumstances a criminal court may rule on damages as part of a conviction for medical malpractice. Such rulings are exceptional, as a damaged party's claim for compensation is usually referred to a civil proceeding.

Civil proceedings in medical malpractice cases are usually initiated after a positive HSCA ruling or successful conviction. Slovak law defines two different types of claims for compensation relating to medical malpractice: compensation for suffered pain and disability, which may be claimed by the damaged person only; and compensation for the infringement of personal rights, which, *inter alia*, includes personal health. These claims are independent.

The calculation of a one-time lump-sum compensation for suffered pain and disability is based on a point scoring system under special legislation. Each specific damage is assigned a certain number of points, and the resulting sum is multiplied by the monetary value of the points, which is updated annually by the Ministry of Health. The point value is set at 2% of the average monthly salary as determined by the Statistical Office of the Slovak Republic for the calendar year preceding the year in which a claim is made. The maximum number of points that can be awarded is in the range of 11,000–12,000.

Damages for an infringement of personal rights may be requested not only by the damaged person but also by his/her close relatives. The highest award to date was a 2013 award of EUR 499,608 for a botched nasal septum operation resulting in the persistent vegetative state of a 15-year-old boy.

Peter Kovac, Head of Lifesciences & Healthcare, Kinstellar Bratislava

CROATIA

Is Pharma Adopting Al Quickly Enough?





Use of Artificial intelligence is growing rapidly. Some of the world's largest industries are using AI as frequently as any other business tool. Still, there are industries which seem to be more risk averse. Pharma integrates AI at the rate of 31% in the service operations sector, 31% in the product/service development sector,

and 27% in the marketing sector. Does that mean that pharma is lagging in implementing AI?

While AI integration is beneficial for business, there are several reasons why the process is somehow slower in the pharma industry than in other industries.

1. Handling of Sensitive Data

In the tech industry, most data is collected from search engines, while pharma collects personal data. Moreover, much of that data is highly sensitive, such as histories of disease, health data, DNA information, *etc.* In addition to the GDPR, many countries have special rules on processing of genetic data. This has proven to be a great regulatory burden for the pharma companies.

2. Risks from Technical Malfunctions

Pharmaceutical companies spend around 15% of their revenues on R&D. If we compare this to other industries, pharma outspends industries like military and aviation (both of which spend around 3% of revenues on R&D) by a five-to-one ratio. Developing a new product on which human lives depend is a risky process. Integrating AI into that process can save money and time, but an error or a glitch could cost human lives and millions of dollars.

3. Complexity of Data Leads to the Complexity of the Al System

The business community has passed through the first and second phase of AI development, and is currently entering the third phase. What does this mean? First-phase AI was good at rea-

soning, but with no ability to learn or generalize; second-phase AI was good at learning and perceiving, but had minimal ability to generalize or reason; the third phase – the one we're entering now – includes AI that has excellent learning, reasoning, and perceptive abilities and average abilities to generalize. Pharma depends on the AI's ability to generalize and reason with huge amounts of unstructured biological data. A lot of time is still spent structuring data before it is input so that the AI is able to process it. With the development of third-phase AI, and later fourth-phase AI, the availability of adequate AI for the pharma industry will increase.

Al and Pharma

There are several areas in the pharma industry into which AI could be integrated, including R&D, the processing of clinical data, individualizing treatments, and complex or rare diseases.

How does AI integrate in pharma R&D currently? Only segments of the R&D process are given over to the AI, and this is still aided by human analysis. This minimizes the risk of error, while still saving time and money.

AI can also be used to make sense of the huge amount of data that pharma companies receive. AI can notice patterns in disease behaviour, occurrence, and treatment from thousands of patients in relatively short periods. This is one of the more promising sectors of the pharmaceutical industry for AI use, yet this is also the sector which is hit most by the GDPR.

AI can play a significant role in individualizing treatments for patients. AI can process and analyze a patient's history faster, better, and more precisely than a human mind. Remote patient monitoring also plays a key role in this sector. Using remote monitoring, a patient can go about his or her daily routine, and AI will collect personal health data and adjust the treatment plan at a moment's notice.

The costs of discovering, monitoring, and treating complex or rare diseases can be drastically decreased with AI.

Pharma is adapting AI as quickly as it can. Pharma-specific risks involved with incorporating AI and pharma-specific required levels of AI complexity are higher than in other industries. AI with good enough reasoning and generalization skills has been developed only recently, and the regulatory burden is greater than in most other industries. So, what can be done to speed up the integration of AI into the pharma business?

The answer lies in collaboration with tech companies, involving mutual agreements or the acquisition of tech companies with developed AI systems. Increased collaboration with academia, through research and development agreements with universities or institutes, would also lead to quicker and easier adaptation of AI into the pharmaceutical industry.

Marija Musec, Partner, CMS Zagreb

ESTONIA

Patient Insurance Reform Has Been Initiated in Estonia





With the June 7, 2019 initiation of the draft Patient Insurance Act, the Estonian Ministry of Social Affairs has achieved an important milestone in the development of the Estonian health care system. This draft act marks a principal change towards the creation of a patient-centric health care system, which will have a major effect on

patients, health care service providers, health care professionals, insurance companies, and society at large.

It has long been discussed that there has been no system of assessment of the quality of the health care services in Estonia. Notably, the National State Audit Office of Estonia decided in 2015 not to conduct an audit of the quality of health care services in the country because, it noted, no basic quality criteria and monitoring system for the assessment of health care services had been set down in Estonian legislation. Also, it has been widely acknowledged that the system of adverse event reporting has not been efficient – a problem exacerbated by the laws establishing personal liability for health care professionals committing errors in treatment.

Patient insurance reform has now been initiated, however, resting on two major pillars: mandatory liability insurance for health care service providers and the creation of an adverse effect reporting system. In addition, the personal liability of healthcare service professionals has been eased.

The obligation to possess liability insurance is expected to be imposed on all health service providers who are licensed to act in Estonia. The liability insurance must cover all health services that are rendered by the health service providers, and the existence of liability insurance will be set as a condition precedent for both issuing and possessing a license to operate as a health service provider in Estonia.

The patients themselves, as well as their heirs, dependants, legal representatives, and certain third persons would be the beneficiaries of the insurance, and these persons would have the right to claim damages for bodily injury, damage to health, or death as a result of the health care service. Patients will have the right to submit their claims to the Patient Insurance Fund, and would have a right of recourse towards the insurer of the health service provider (in case damages are paid to the patient). The Patient Insurance Fund would pay out patient claims even where the health service provider has violated its obligation to obtain liability insurance.

The Expert Committee of Health Care Service Quality has also been reorganized. Previously, the Committee was in charge of assessing the errors of treatment, but the decisions of the Committee were not binding on the health care service providers, and the Committee did not have any role in ordering compensation for damages. The Committee will now, however, have new competences; it will resolve patient complaints against the Patient Insurance Fund and it will be a mandatory pre-trial institution for the settlement of patient claims against the Patient Insurance Fund.

In relation to adverse effect reporting, the draft Act proposes amendments to the criminal liability of health service professionals. Specifically, if the health service professional reports an adverse effect, criminal proceedings against the professional could be terminated. The amendment is designed to create a non-punitive system focusing on reporting adverse effects rather than penalizing errors by health care professionals.

This reform has not been greeted with overwhelming enthusiasm. The insurance coverage has been set at EUR 100,000 per insured person, EUR 300,000 per insurance case, and EUR 3 million per insurance period. Representatives of the health care service providers have been critical of the levels of protection to be granted to patients, noting that these amounts far exceed the levels of protection previously afforded to Estonian patients and that providing such levels of protection would significantly increase insurance costs, leading to potential shortcomings in the availability of health care services.

The current draft act is expected to enter into force on July 1, 2021, but there is a long governmental and parliamentary process that it must go through first, so interested parties will have an opportunity to voice their opinions on the reform.

Elo Tamm, Partner, Cobalt Estonia

NORTH MACEDONIA

New Law on Phytopharmacy in North Macedonia





It is no secret that North Macedonia is facing the issue of usage of products for plant protection which often fail to meet legal standards. Namely, Macedonian manufacturers producing agricultural products for human and animal nutrition often use unauthorized products which fail to meet safety criteria and may have suspicious origins. Although this issue

is not as widely-discussed as air pollution in North Macedonia, it contributes significantly to the existing environmental pollution problem and has a huge impact on the health of plants, people, and the environment.

In addition to poor ecological awareness, lower prices, and an "aggressive efficiency" justification, one of the reasons for this practice is the failure of North Macedonia's current Law on Products for Plant Protection to tackle the issue. The current law is ineffective for several reasons, the main one being a poor system for control of the products for plant protection imported into the country.

This matter has already been identified by some NGOs and the trade organizations in the past and passed along to the Macedonian Ministry for Agriculture, Forestry and Water Economy. As a result, a new Law on Phytopharmacy is expected soon.

The new draft Law on Phytopharmacy has been approved by the Macedonian Government, and once adopted by Parliament, it will partially harmonize the legislation with EU *acquis*, either by direct implementation (*e.g.*, the transposition of Regulation 1107/2009 on placing and advertising of phytopharmaceutical products and Directive 128/2009 on sustainable use of pesticides) or by providing the basis for indirect harmonization with other EU legislation (*e.g.*, the regulation on collecting phytopharmaceutical usage data, marking phytopharmaceutical prod-

ucts, monitoring programs, using equipment for application of phytopharmaceutical products). The harmonization with the EU regulatory framework will be made only partially though, as some provisions in the EU code apply only to member states and will be transposed into North Macedonian law once the country becomes a member state, or is in a more advanced phase of accession.

Overall, the new Law on Phytopharmacy is expected to assure greater protection of plants and further regulation and control of the use of pesticides and the application of non-pest control measures, which should ultimately result in a higher level of protection of human and animal health and overall environmental protection.

The expectation for the higher efficiency of the new Law on Phytopharmacy is based on the following elements: (i) a more sophisticated regulation of the import, packaging, labelling, advertising, and placing on the market of products for plant protection (identified as phytopharmaceutical products under the new Law on Phytopharmacy); (ii) continuous monitoring of food safety, including animal food, in the chain of plant production; (iii) mandatory training and licensing of all legal entities and professional users of pesticides, as well as controlling, testing, and certifying of equipment for use on phytopharmaceutical products; (iv) introducing a phytosanitary information system electronically connected to all users that will enable the mandatory recording of the sale (by the legal entities) and the use (by the users) of phytopharmaceutical products; (v) a more detailed regulation of the emergency approval process for phytopharmaceutical products, as well as stricter rules for import of phytopharmaceutical products via border crossing points with access to adequate control facilities; and (vi) the placing of phytopharmaceutical products containing GMO and other living organisms on the market only if the product fulfils the conditions in the GMO regulation.

By implementing these mechanisms, the authorities will have oversight and control of the import, sale, and use of phytopharmaceutical products and the equipment for their application, and they will be able to better educate all people that have contact in any manner with pesticides. Once the import and placement of phytopharmaceutical products on the market is harmonized with EU standards, the quality and the safety of the products should increase, and the placement of unauthorized phytopharmaceutical products on the market should be prevented.

Although there is no information on when the new Law on Phytopharmacy will be adopted by the Parliament, we hope that the urgent need for the law will be recognized by the Parliament and that North Macedonia will soon be able to reach EU standards in this area.

Marija Filipovska, Partner, CMS Macedonia

HUNGARY

Recent Trends Relating to Industrial Cannabis: New Investment Opportunity in CEE?





The worldwide legal marijuana trade has grown significantly in recent years. According to some sources, the United States accounts for a global market share of 90 percent of all legal marijuana traded.

Although the global legal marijuana trade is projected to increase,

the use of cannabis is still a highly controversial topic in the CEE region. In several CEE countries, such as the Czech Republic, Bulgaria, and Romania, production and use of medical cannabis is allowed, although it is strictly regulated. However, in some other countries in the region – in particular, in Slovakia, Hungary, and Serbia – the use of marijuana is still under debate.

As opposed to medical cannabis, there is a greater understanding across Europe regarding industrial cannabis (industrial hemp), especially regarding the use of cannabidiol (CBD), which is one of a class of chemical compounds known as cannabinoids that are inherent in the cannabis plant. CBD is not known to cause psychoactive effects, unlike cannabinoid tetrahydrocannabinol (THC), which is the primary psychoactive compound in marijuana.

While scientific research carried out over the past few years has confirmed significant therapeutic attributes of both compounds, unlike THC, CBD does not make a person feel intoxicated. It is considered a non-addictive substance that alleviates pain and certain symptoms of disorders such as epilepsy, while also potentially mitigating the side effects of chemotherapy.

While THC's benefits remain the subject of strong debate, the focus has shifted to CBD. Currently, a wide range of products containing CBD, including cosmetics and food supplements, has become available on markets around the world. As a result of what are believed to be CBD's positive effects on the human body, a great deal of interest has been expressed in this industry.

Hungarian Regulatory Background and Practicalities

Hungarian law defines "cannabis" as any flower or branch of the cannabis plant (apart from the seeds) whose resin has not been extracted yet. In accordance with the International Convention on Narcotic Drugs (1961), cannabis and its derivatives (cannabis resin, extracts, and tinctures of cannabis) are considered to be narcotics



in Hungary, and the cultivation, use, distribution, and any other activities related to cannabis are strictly regulated in Hungary.

The main Hungarian regulatory authority regarding cannabis-related activities is the National Institute of Pharmacy and Nutrition, at which notifications are made and licences are obtained. Other authorities (e.g., the National Food Chain Safety Office) may also have competence depending on the contemplated activities, as well as the nature and intended purpose of the end product. As there is a detailed regulatory framework applicable to cannabis-related activities in Hungary, notification and licensing requirements need to be examined on a case-bycase basis, taking into account all business, legal, and technical details and the circumstances of the contemplated cannabis-related activities.

Under Hungarian law, a distinction is made between "low-THC content hemp" and "high-THC content hemp," with "hemp" being defined as all plants of the genus Cannabis. Low-THC content hemp means fibre hemp and seed hemp belonging to the so-called "Cannabis sativa L. Species" with THC content (de facto or according to the results of the relevant examination) of less than 0.2 percent, not including roots and stems, in an air-dried, homogenized state. High-THC content hemp means any type of hemp that does not qualify as low-THC content hemp, i.e., with THC content exceeding 0.2 percent in the same parts of the plant.

In order to carry out any cannabis-related activities (*i.e.*, with both low and high THC content hemp) in Hungary, detailed notification and licensing requirements must be complied with. The extent of these requirements depends primarily on the following factors: (i) the THC content of the hemp and the end product to be produced from the hemp; (ii) the contemplated activities to be carried out in Hungary (manufacturing, export, import, transfer, distribution, research, *etc.*); (iii) the extraction method used during the manufacturing process (*e.g.* simple cold pressing or supercritical CO2 extraction); (iv) contents of the end product; and (v) the nature and intended use of the end product (*e.g.* cosmetics, food supplements).

Akos Nagy, Partner, Eszter Takacsi-Nagy, Associate, and Bianka Pandur, Junior Associate, Kinstellar Budapest

SERBIA

The New Law on Healthcare Protection



At the beginning of April 2019, the Serbian Parliament adopted the new Law on Healthcare Protection (the "Law"), with the aim of improving the legal framework and facilitate better functioning of the healthcare system in Serbia, aligning it more closely to EU standards in this field.



This new piece of legislation introduces significant novelties to the healthcare sector, including the registration of healthcare institutions with the local Business Registers Agency, the liberalization of healthcare institution advertising (public and private), specific rules concerning the engagement of healthcare prac-

titioners (HCPs) from public healthcare institutions in private practices, introducing rules for HCPs receiving gifts, and new prevention programs for patients.

New Rules on Healthcare Institutions

One of the key novelties provided by the Law is a new rule concerning the registration procedure for healthcare institutions. Specifically, as of October 11, 2020, public and private healthcare institutions will be obliged to register in the Register of Healthcare Institutions, which is to be established within the Serbian Business Registers Agency – the central authority for wide variety of registers. The newly established register will include very detailed information on each healthcare institution, including its name and type, information about its founder, the date and number of the license for the fulfillment of the prescribed conditions in order to perform healthcare activities issued by the relevant Ministry, working hours, etc. Currently, healthcare institutions are required to provide only limited information in registering with the Commercial Court, and there is no publicly available register.

Further, under the new Law, all public healthcare institutions are deemed to be founded either by the Republic of Serbia or by its autonomous provinces, *i.e.*, the new Law canceled the previous rule that primary healthcare institutions should be owned by the local government.

Additionally, for the first time, healthcare institutions can now be founded as public private partnership projects, allowing the conjunction between the state and private capital to push for overall improvement of the healthcare protection system in Serbia.

Advertising of Healthcare Services

The previously applicable Law on Healthcare Protection was very strict regarding the advertising of healthcare services and allowed only a limited amount of information to be provided to patients, including the name and type of health institution and its seat and working hours. However, the new Law significantly liberalizes the rules in this regard, and public and private healthcare institutions are now allowed to advertise healthcare services, expert-medical procedures, and methods of healthcare protection in accordance with the registration license issued by the Ministry of Health, as well as contact details, with the aim of providing patients with necessary information.

Supplementary Work of HCPs

The new Law regulates, in a more precise manner, the supplementary work of HCPs by prescribing that they can enter into an agreement for supplementary work with their employers or with a maximum of three other employers for a maximum of one-third of the full-time working hours. As a precondition for the performance of supplementary work, the HCP has to obtain the prior consent of the director of the institution where the HCP performs his or her full-time working hours. Consent has to be provided within five working days from the request, and under the condition that the HCP fulfills certain requirements.

The validity of the consent is one year.

Conflict of Interest

The Law introduces separate provisions regulating conflicts of interests, anti-corruption requirements, and thresholds for HCPs receiving gifts. An individual gift (*i.e.* each specific gift) cannot exceed 5% of an average monthly net salary in Serbia, and all the gifts received during a one-year period cannot exceed the amount of an average monthly net salary in Serbia.

Unlike the Law on Anti-Corruption Agency, which includes the same threshold, and requires that any gift received by an official must be received in its total amount (one average month's salary) within one year, the new Law on Healthcare Protection does not stipulate the period of time in which a gift must be completed, and consequently opens the door for potential corruptive activities. This gap in the Law has been widely criticized by experts and is expected to be changed in the future.

Goran Radosevic, Partner / Independent attorney at law, and Milica Filipovic, Senior Associate / Independent attorney at law in cooperation with Karanovic & Partners

ROMANIA

Regulators' Feeble Attempts to Calm the Pharma Market and Ensure Patient's Access to Necessary Therapies



A review of the Romanian pharma market reveals the real challenges faced by pharmaceutical companies and the impact of those challenges on patients.

Whereas the funding shortage affecting the healthcare sector – particularly the medicines budget – is not specific to Romania, the

lack of coherent and efficient mid- and long-term health policies, as well as restrictive and unpredictable pharma laws, have unfortunately been a consistent feature of the country's pharma market over the years. As a result, industry players encounter difficulties in drawing up multiannual (or even annual) budgets, and on patients' access to essential therapies.

A Pileup of Restrictive Measures

Most European countries have regulated instruments to limit and control public expenditure on medicines. In Romania, however, sometimes confusingly, several measures are applicable, including: the minimum European price (benchmarked against 12 low-price countries); an additional price reduction for generic and biosimilar medicinal products, benchmarked against the price of matching innovative medicinal products; a public system reimbursement price consisting of a percentage of the lowest price for the therapeutic unit of the international non-proprietary name (INN); a non-transparent clawback tax for all medicines reimbursed from public funds; restrictive procedures for the assessment of health technologies or related to the conclusion of managed entry agreements; and the prescription of expensive medicinal products according to strict therapeutic protocols.

Unsurprisingly, these measures have led to many medicines missing from the market, including many of the cheapest ones (over the past two years, more than 2,000 withdrawal applications were registered with the National Agency for Medicines and Medical Devices (NAMMD)), the migration of essential medicines to parallel trade, and restrictions on market entry for innovative therapies.

Legislative Measures to Limit the Disappearance of Medicines

At the eleventh hour, Romanian authorities seem to have grasped the scope of the problem, and they adopted several limitation measures.

Thus, the status of clawback tax, which was instituted in 2011 by Government Emergency Ordinance No. 77/2011, has been recently amended to give a much-needed breather to marketing authorization holders (MAHs) and allow them keep medicines on the local market. Although the tax was initially introduced as a temporary crisis measure, it became permanent, and proved to be an unsustainable burden for MAHs, which are legally bound to subsidize the budget of reimbursable medicines by growing percentages, exceeding 25% in the 4th quarter of 2018 (which is basically the entire budget overrun approved by authorities).

Under the recent Government Emergency Ordinance No. 28/2019, published on May 8, 2019, GEO No. 77/2011 was amended by increasing the quarterly budget for medicines covered from public funds from RON 1.515 million to RON 1.595 million, a small relief for MAHs' tax burden. Also, in response to acute shortages of essential medicines, the Government has already issued two other ordinances (GEO No. 111/2018 and GEO No. 100/2017), exempting certain vaccines and human blood or human plasma derivatives included on the lists approved by order of the Ministry of Health (MOH), from the payment of clawback tax.

Despite failing to remedy the main causes for the exodus of medicines, the MOH adopted certain measures to address medicine shortages. Thus, MOH Order No. 269/2017 on the obligation to ensure adequate and continuous stocks of medicines added control instruments to those provided in Directive 2001/83/EC. Accordingly, as regards medicinal products subject to reimbursement, MAHs must provide a monthly minimum level equal to the average monthly turnover for each medicine in their portfolio, while wholesale distributors must set up a buffer equalling the average monthly turnover for each such distributed product. The NAMMD will be informed of any failure by distributors and secondary MAHs to comply with pharmacies' and hospitals' legitimate orders and may declare a national alert on severe medicine shortages. In this case, the MOH may further place the relevant medicine on the so-called Temporary List of Medicinal Products Under Surveillance, which includes products that are temporarily banned from intracommunity delivery and export.

Finally, measures have been taken for the regulation and transparency of HTA processes and the conclusion of managed entry agreements. However, many regulatory and budgetary restrictions are still in place as regards the reimbursement of innovative therapies, and significant delays may still be encountered in the assessment process.

It remains to be seen, in this critical year, whether a balance will be found between patient needs, the legitimate requirements of pharma companies, and the need to control State budget expenditures.

Dominic Morega, Head of Pharma Law, Tuca Zbarcea & Asociatii

TURKEY

The Classification of Medicinal Products in the European Union and Turkey



Advertisement is a very strong instrument in free market economies like Turkey's. As a bridge between manufacturers and consumers and in light of its contribution to a competitive market, the importance of advertisement is critical.

In this article, we would like to discuss restrictions on advertising applicable to both prescrip-

tion and nonprescription (sometimes called "Over the Counter", or OTC) medicinal products in both the countries of the EU and Turkey.

Advertising Restrictions in Accordance with Medicinal Products' Classifications

On March 31 1992, four EU directives came into force resolving legislative differences about medicinal products. One of them is Directive No. 92/28, which states that medicinal products may be advertised to the general public if, by virtue of their composition and purpose, they are intended and designed for use without the intervention of a medical practitioner for diagnostic purposes or for the prescription or monitoring of treatment, with the advice of the pharmacist.

Any informative actions and any campaign or encouragement actions made in order to increase the recommendation, sale, and supply or the consummation of medicinal products are also considered advertising under the directive.

In any advertisement of a medical product, it should be clearly stated that the message is an advertisement, and the product should be clearly defined as a "medicinal product." The formal and common name (if any) of the medicinal product and the information required for its correct should also be included.

Directive No. 92/28 prohibits the advertising of medicinal products which are available only with a prescription, contain psychotropic or narcotic substances, publicize treatment methods of tuberculosis, sexually transmitted diseases, other serious infectious diseases, cancer and other diseases involving tumors, chronic insomnia, diabetes and other metabolic illnesses; the cost of medicines which may be reimbursed and distribution of medicinal products to the public by the industry for promotional purposes to the general public.

In Turkey, Article 13 of the Pharmaceuticals and Medical Prepa-

rations Law dated 1928 regulates the advertisement of prescription and nonprescription medicinal products. This law forbids the advertising of medicinal products by stable or moving cinema films, illuminated or non-illuminated billboards, and on radio or any other media with a view to praise the preparation or to exaggerate its therapeutic results. However, the law permits announcements that the medication "is useful in treatment of __ diseases" in prospectuses and daily newspapers. The advertising of prescription medicinal products is strictly prohibited in any place other than medical publications.

Samples of any advertisements have to be approved, in advance, by the Ministry of Health. In addition, films prepared regarding the scientific properties of a preparation may be shown with the permit of the Ministry of Health only at the places indicated by the ministry.

In addition to this legislation, Article 4/d of Regulation on Advertisement of Medicinal Products for Human Use came into force in October 23, 2003 complying with EU legislation. It defines advertisement as actions of license or permit owners including but not limited to reminder, notification, actions of medical sale representatives of companies, presentations put on audiovisual press, medical publications, notifications made directly by post or internet, exhibitions and similar actions alongside with giving away samples free of charge, promotions and printed publication materials in order to increase the supply, sale, prescription and use of medicinal product for human use.

But the execution of Article 4/d has been suspended by the decision of 10th Chamber of Council of State numbered 2003/5945E dated October 12, 2004, and other relevant articles have been cancelled since. Even though Turkish law allows advertising of nonprescription medicinal products limiting only to gazettes and prospectuses; the regulation allowing advertisement of nonprescription medicinal products by any means, including radio and television in accordance with EU legislation was deemed unlawful.

Conclusion

Many who support changing this law and allowing for free advertising believe that informing the general public of the ingredients and effects of products will be beneficial for public health. On the other hand, others believe that allowing the advertising of these products will increase improper and use and damage public health. Even though new draft laws in cooperation with EU legislation are being discussed, at the moment, advertisement of nonprescription medicinal products can be conducted only through gazettes and prospectuses in Turkey.

Nazli Sezer, Executive Partner, Sezer & Utkaner

BULGARIA

Health Tech - 3 Questions, 3 Industries, 3 Points of View



At the end of April, 2019, Sopharma Trading announced the creation of "SOinventure" – a corporate acceleration program in the field of health-tech, organized in partnership with Bulgarian investment fund Eleven Ventures. We decided to ask Mr. Ivaylo Simov, Partner at Eleven Ventures, and Mr. Dimitar Dimitrov, CEO

of Sopharma Trading, three questions about the development of the alliance between healthcare and new technology, and we added our experience-based opinion to their answers.

Q: How will healthcare benefit from new technology?

Ivaylo Simov: Software is eating the world and pharma and healthcare are next in line. As in all other industries, new technologies introduce benefits both for businesses and their clients, no matter if they are b2b or b2c. Technology will bring down costs and make services and products more easily and readily available to the right client at the right time.

Dimitar Dimitrov: I believe that innovation and technologies will completely redefine healthcare and have the potential to improve the quality of our lives tremendously. Still, this change depends on us! That is why we started SOinventure – as an innovation program to re-design healthcare and make the most of the huge potential innovation & technology possess.

Elena Todorova: New tech usually kills bureaucratic thinking. The healthcare sector is over-regulated and often associated with vague procedures and enormous amounts of paperwork. My expectation is that the technology will turn healthcare into a patient-friendly and tailor-made service.

Q: Where are the challenges for uniting new tech and healthcare?

Dimitar: Some challenges are visible now, others will come on the way. As we all know the most difficult thing is not to have new ideas, but to make people forget the old ones! Our goal – to create a new, unique patient experience throughout all stages of the patient journey – is truly ambitious, considering that the current healthcare system operates far differently than the technology sector does. And here comes the first challenge: how these two diametrically different-by-nature industries might cooperate.

Ivaylo: One of the biggest challenges that we are trying to resolve is: how do you manage to connect a small and nimble start-up to a large pharma corporation or healthcare provider? Accepting new ideas and models of work is tougher the older and more regulated an industry is.

Another thing to note is the difference between the workflow and processes in small start-up teams compared to large pharma companies. One has established processes and organizational structure supporting steady and secure growth, where the other works on high gears of speed and iterations, allowing for agility and adaptability.

Elena: Our challenge here is to put the alliance between quick innovation and the responsibility for human life on a sustainable foundation. And as legal acts do not have the necessary dynamics of development, the postulates of justice, ethics, and morality are back on the agenda. This is a test for jurists accustomed to relying on the letter of the law.

Q: What is the next hype trend in the industry – nanomedicines, AI, blockchain-based platforms, or something else?

Dimitar: I would say all of them! All these innovations, technologies, etc. I see them working in a holistic way as part of a new fantastic ecosystem. All we need to do is connect the dots from the perspective of patient needs. This is the primarily goal of SOinventure - to engage innovation & technologies and build a brand-new healthcare focused on the patient!

Ivaylo: The next big thing will be incremental improvements across the board and making sense of the big data out there, and then - connecting the dots indeed. As we always say, innovation happens at the crossroads of industries and science, and there's no better field than healthy living for this to happen in.

Most technology trends will have their impact on the health industry in one way or another. The new treatments such as stem cells and personalized medicines will also need to go the long way of clinical trials before reaching patients. Yet, big pharma companies are also exploring how digital medicine and wearables, for example, can supplement or replace existing drug treatments today.

We believe that the future of health is built by a mix of established and emerging technologies which complement and support each other.

Elena: Perhaps artificial intelligence. The EU has already agreed on a definition of AI. The next big step could be to regulate the liability that AI could carry.

Elena Todorova, Head of Healthcare and Life Sciences, Schoenherr Bulgaria

LATVIA

Scrutiny of Industry Practices by the Competition Authority Continues





In late 2018, the Competition Council of the Republic of Latvia published the final report on its most recent in-depth sector inquiry on the distribution practices of reimbursed medicines on the wholesale market and potential competition restrictions therein. The sector inquiry had lasted for almost two years, during which

the Competition Council gathered information from both the public and the private sectors, approaching seven producers, twelve wholesalers, and several public institutions, such as the State Agency of Medicines and the Health Inspectorate, among others. Although the Competition Council proclaimed that the main goal of the sector inquiry was to analyze potential competition restrictions on the wholesale market, which could be apparent because of the vertical integration of wholesalers and leading pharmacy chains and the exclusivity status of the wholesalers, no infringements proceedings were initiated as a result. Notwithstanding the lack of subsequent infringement proceedings, however, some crucial conclusions were drawn.

First, the Competition Council concluded that the average price of B list reimbursable medicines had increased 20% in only three years. Second, the Competition Council singled out AS Recipe Plus as the market leader with the most significant market power that lacks effective competition on the wholesale level. Third, the Competition Council emphasized that the vertical integration of leading wholesalers and pharmacy chains and the limited direct contracting between the producers and the wholesalers create a risk that existing market participants will be excluded and that new ones will have difficulty entering. Fourth, the Competition Council identified systemic problems in the distribution of medicines that have resulted in problems for patients seeking access to reimbursed medicines.

Following the publication of its final report, the Competition Council asserted that one of its priorities in 2019 will be further

investigations and inquiries within the pharmaceutical industry. The Competition Council has certainly been living up to this, and on May 2019 it sent in-depth information requests to a majority of leading market participants, indicating that another sector inquiry has been initiated. What is unusual in relation to this specific sector



inquiry is that the Competition Council is not looking at pricing policies in the Latvian market alone, but in the Baltics as whole.

According to the requests it sent to the market participants, the Competition Council has opened a sector inquiry "on factors affecting drug prices and potential restrictions of competition," and it is focusing a significant amount of attention on existing contractual relationships between wholesalers and manufacturers, as well as on individual practices of producers in relation to their choices in use of specific marketing activities, the allocation of funds for these activities, and their impact on the final price offered to wholesalers. The Competition Council has inquired not only about the prices offered by producers to wholesalers, but also about the specifics of rebate schemes employed in all three of the Baltic jurisdictions.

From the questions posed in the requests, it appears that the Competition Council is concerned with the differences in pricing practices, which are heavily influenced by a few leading wholesalers exercising strong purchase power. Although it is speculative to assume that any of the market participants are holding dominant market position in any of the relevant markets, the Competition Council's inquiries imply deep interest in the causes of the previously-mentioned systemic problems that consumers are facing.

It is yet to be seen how the sector inquiry will advance, given that it took almost two years for the final report to be published last time. And more inquiries for information might follow, depending on the scope and content of information provided by the market participants in relation to the most recent requests. It is even less clear what will be the course of action of the Competition Council in relation to the use of information about the Baltics as a whole, given that the direct exchange of information happens between national competition authorities.

Nevertheless, it is clear that regulatory authorities are ever more inclined to engage in analyses of problematic aspects of the pharmaceutical industry, resulting in increased potential for new regulatory enactments or possibly even infringement proceedings following the closing of the sectoral inquiry.

Indrikis Liepa, Partner, and Janis Sarans, Attorney, Cobalt Latvia

RUSSIA

Enforcement of Pharmaceutical Patent Rights in Russia: New Opportunities?



The enforcement of pharmaceutical patent rights in Russia is a multi-aspect issue. One such aspect, well known to the industry and patent owners, is the attempt to prevent pharmaceuticals that may infringe on prior patent rights from being registered by the Russian healthcare authorities.

At present, the patent protection system and the pharmaceutical state registration system are two totally distinct worlds with little inter-connection.



In Russia, patent rights are granted to IP owners by the Russian Patent Office ("Rospatent") following an examination on the merits and subsequent registration. In line with most countries, Russian affords patent protection to substances, including pharmaceutical substances. A patent to an active pharmaceutical ingredi-

ent (API) of a pharmaceutical, once granted, allows the patent owner to use the API and legally prevent other parties from using products bearing features of the protected API. Under the Russian Civil Code, infringing use includes such actions as importing the products to Russia and manufacturing, offering for sale, and sale.

However, what if an alleged infringer has not yet started to actually produce or commercialize the conflicting product but has undertaken actions to apply for the state registration of a pharmaceutical that bears features of a registered patent of a senior patent owner? Can the patent owner prevent this?

The current system for registering pharmaceuticals with the Russian Ministry of Healthcare (the "Ministry") does not envisage the verification of prior patent rights. This has led in the past to numerous discussions and disputes.

Court Rulings

The courts have tended to refuse to recognize actions involving the registration of a disputed pharmaceutical as constituting patent infringement. One of the examples is the *Novartis AG* vs. *Pharm-Syntez* dispute. Courts of several instances ruled in favor of Novartis, but the Higher Arbitrazh Court, in its ruling of June 16, 2009 (No. 2578/09), reversed the earlier decisions and ruled that, while the manufacture by Pharm-Syntez of the

conflicting pharmaceutical was an infringement and must be prohibited, the registration of the same pharmaceutical is *per se* not infringing, as it is not an infringing use and is not prohibited under patent legislation.

Over time the situation has gradually begun to change.

For example, in the *Novartis AG vs. Nativa* dispute, dated September 27, 2017 (No. A41-85807/2016), the Arbitrazh Court of the Moscow Region recognized actions involving the registration of a conflicting pharmaceutical with the Ministry as creating the threat of a patent infringement.

Furthermore, in the Astra Zeneca vs. Jodas Expoim dispute the Court on Intellectual Property Rights, in its ruling of February 28, 2019 (No. A40-106405/2018), ordered the defendant to file an application with the Ministry to withdraw the registration of the conflicting pharmaceutical, as well as an application to remove from the state register marginal sales prices applicable to "essential" pharmaceuticals. The court also prohibited the defendant from performing actions aimed at the registration of the pharmaceutical for as long as the claimant's patent remains valid. The reasoning for this ruling was the qualification of the defendant's actions as creating preparatory actions for an infringement.

One Step Further

Patent owners are now more actively trying to influence the Ministry into improving the state registration system of pharmaceuticals.

As a result, Rospatent, supported by representatives of the industry, has recently come up with the idea of creating a state register of APIs protected by Russian patents for inventions. As proposed by Rospatent, this register should contain information on the patents for APIs and details on the owners.

The Ministry, in its turn, will update this register with relevant information about the registration of potentially conflicting pharmaceuticals, introducing, where applicable, restrictions on their use (e.g. only allowing such pharmaceuticals to be released into circulation upon the expiry of the patent rights of the original pharmaceutical manufacturer).

The mechanism of interaction between Rospatent and the Ministry and many other details still need to be developed and, if this process is successful, the concept will proceed to the draft law stage. It is intended that the register will be implemented before the end of 2019.

The register, if implemented, may help prevent the state registration of pharmaceuticals that infringe on existing patents and combat patent infringers, which, at the moment, wastes enormous time and effort and sometimes allows infringing pharmaceuticals to enter the market and be supplied to state entities and pharmacies.

Julien Hansen, Partner, Pavel Arievich, Legal Director, and Julianna Tabastajewa, Counsel DLA Piper



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