STRATULAT ALBULESCU
ATTORNEYS AT LAW

TALKING SAA

SAA empowers the team and its communications skills on a great teambuilding trip

It builds trust, mitigates conflict, encourages communication between people, and definitely increases collaboration. This is why we believe that effective team building means more engaged employees, improved productivity and motivation which are good for the entire team. We all know that spending time together, sharing an experience or working towards a common goal allows bonding to happen more organically and far more effectively.

This year we chose the beauty of the mountains, fresh air and lots of snow and went on discovering as many ski slopes as possible in Poiana Brasov, the best known Romanian ski resort at an altitude of 1030 m. Located in Brasov County, Poiana Brasov is the most appreciated Romanian resort and we believe it's the perfect place where anyone can enjoy the adrenaline on the best slopes, if you are somewhat experienced in skiing and snowboarding. With a breath-taking scenery, fabulous snow and good restaurants, Poiana Brasov was the perfect place to go and break down all barriers, eliminate distractions, and have fun.

Being aware of the fact that great communication begins with connection, the team also enjoyed improving communication skills by attending a session of "Teamwork and Communication" training. The course focused on the main idea that good communication amongst teams is successful not necessarily when everyone agrees on every topic, but when the dialogue continues in spite of disagreements.

So, we definitely shared the benefits of our teambuilding, got to know each other outside of work and shared experiences that drew us together and gave us stories to tell. Because working together with friends, not only colleagues, makes us feel like we're part of something bigger than ourselves.

SAA´s Managing Partner Silviu Stratulat and Partner Ramona Iancu participated in 7th IBA European Corporate & Private M&A Conference in Paris, France, on 7-8 February 2019

This International Bar Association (IBA) conference provided a great opportunity for our team to meet with other colleagues from several different countries and gain up-to-date knowledge of the key developments in our areas of law.

Debated topics that got everyone's attention included Data protection matters, potential risks between signing and closing in European M&A deals and how to run a dual track transaction in Europe. The sessions looked at some of the latest trends and developments in European private M&A, best practices and several challenges that arise at each stage of the M&A process**.**

We are pleased to have participated in such a stimulating complex and interesting event that enabled us to hear from leading international figures, acquire greater knowledge and build further invaluable international connections with leading practitioners worldwide.

Inspired by the vision of the United Nations, the IBA was established in 1947 and covers all practice areas and professional interests facilitating the exchange of information and views among its members as to laws, practices and professional responsibilities.

LEGAL UPDATES

REAL ESTATE

Amendments to legislation regulating the award of concession contracts

As of January, 2019, the provisions of Article 38(8) of Directive 2014/23/EU of the European Parliament and of the Council (the "Directive") were amended by the latest corrigendum (the "Amendment").

In the light of the Amendment economic operators shall be compulsorily and explicitly excluded from participation in a concession award procedure, if they have been involved in the situations provided under Article 38(4) and (5) of the Directive (i.e. participation in a criminal organisation, corruption, fraud, terrorist offences, money laundering or terrorist financing, child labour and other forms of trafficking in human beings, breach of obligations relating to the payment of taxes or social security contributions). Thereby, the previous possibility that contracting authorities and contracting entities could exclude those economic operators who are in one of the aforementioned situations became an obligation pursuant to the Amendment.

The original wording of the Directive has been transposed into national law by Law no. 10/2016 on works concessions and services concessions (hereinafter "Law 10/2016"), and thereto Article 83 of Law 10/2016 is the equivalent of the aforementioned Article 38(8) of the Directive.

The new amended wording of the Directive, as introduced by the Addendum, is however still to be transposed into national law. Therefore, a revision of the abovementioned Article 83 of Law 10, is necessary and compulsory. Nevertheless, no deadline was specified or announced within the Amendment, or by the competent Romanian authorities.

We shall keep this issue under review and keep reporting on any further proposals to amend the Law 10/2016, which may be published for public debate.

LIFE SCIENCES AND HEALTHCARE

Data privacy related amendment to Law No. 46/2003 on patient's rights

The patient's right to access his/her personal medical data was amended to include the patient's right to designate, by an agreement listed in the annex to the general Clinical Observation Sheet, a person who can have full access, both during the patient's life, as well as after the patient's death, to the confidential information in the Clinical Observation Sheet.

Law No. 347/2018 for amending art. 24 of Law No. 46/2003 on patient's rights was published in the Official Gazette of Romania No. 3 as of 3 January 2019.

Amendment to the procedure for appointing Ministry of Health's specialist committees' members

On 3 January 2019, Order No. 1614/2018 amended Order No. 1202/2017 on the establishment, organization and functioning of Ministry of Health's specialist committees and subcommittees.

The updated procedure provides that members are appointed by the Ministry of Health following consultation with industry-specific universities, professional organizations and the Romanian College of Physicians or, as novelty, following proposals by the specialist committees' chairpersons.

Order No. 1614/2018 was published in the Official Gazette of Romania No. 6 as of 3 January 2019.

Temporary authorizations for medical devices marketing and services activities

Order No. 3/2019 entered into force on 4 January 2019 to amend Order No. 1008/2016 on approval of the Methodological Norms for applying title XX of Law No. 95/2006 on the health reform, regarding authorization of medical devices related activities.

For ensuring continuity of medical devices related activities in need of authorization by the National Agency for Medicines and Medical Devices ("NAMMD"), i.e. (a) import, (b) storage and distribution, (c) repair, maintenance and installing/ commissioning, (d) medical optics, and (e) prosthetics, NAMMD issued temporary operating authorizations valid until the date of issuance of the authorizations to be obtained as per Law No. 95/2006, no later than 30 June 2019.

Such temporary authorizations were only issued for holders who had submitted the documentation for conversion of the authorizations, these being issued within 7 days as of entry into force of Order No. 3/2019.

For operating authorizations holders for which NAMMD issued a positive evaluation report before 4 January 2019, operating authorizations are awarded according to the general rules (i.e., within 15 days as of the date of the evaluation report).

Order No. 3/2019 was published in the Official Gazette of Romania No. 11 as of 4 January 2019.

Amendment to the Loan Agreement between Romania and IBRD on the health sector reform project (the "Project")

The Loan Agreement between Romania and the International Bank for Reconstruction and Development (IBRD) was signed on 17 June 2014 and is in force since 23rd of December 2014. The financed Project focuses on implementing the health sector reform by improvement of quality and efficiency of the sanitary system.

The total funding value for the Project is of EUR 250 mm, out of which approx. EUR 60 mm has already been drawn.

In October 2018, the second amendment to the Loan Agreement for the Project (the "Second Amendment") was signed, and afterwards approved through Government Decision No. 1004/2018 in force since 3 January 2019. The amendment does not increase Romania's obligations towards IBRD.

By way of this Second Amendment, following a reassessment of the current necessities and implementation conditions, the objectives of the Project were slightly adjusted in order to better focus on strengthening access to public health services and their quality, as well as consolidating the main scope of saving lives, including through cancer screening, improvement of the health infrastructure (by rehabilitating existing medical units and building 4 new ones) and supporting the Ministry of Health and other government institutions' activity for the proposed goals.

Government Decision No. 1004/2018 was published in the Official Gazette of Romania No. 7 as of 3 January 2019.

Amendment of the EU medicinal products for veterinary use legal framework

Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No. 726/2004 of the European Parliament and of the Council constituted the European Union's regulatory framework for the placing on the market, manufacturing, import, export, supply, distribution, pharmacovigilance, control and use of veterinary medicinal products.

Following the assessment by the Commission of the functioning of the internal market for veterinary medicinal products, it was considered that the regulatory framework for veterinary medicinal products should be adapted to scientific progress, current market conditions and economic reality, which lead to the adoption of Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (the "Veterinary Regulation").

Considering that the needs of the veterinary sector differ substantially from those of the human sector in relation to medicinal products, and the size of the animal pharmaceutical industry is only a small fraction of the size of the pharmaceutical industry for medicinal products for human use, the new regulatory framework addresses the characteristics and specificities of the veterinary sector, which cannot be considered as a model for the medicinal products for human use market.

The Veterinary Regulation takes into account the needs of businesses in the veterinary pharmaceutical sector and trade in veterinary medicinal products within the European Union. It also aimed to integrate the major policy objectives set out in the Communication from the Commission of 3 March 2010 entitled "Europe 2020 A Strategy for smart, sustainable and inclusive growth".

The Veterinary Regulation thus:

(I) aims to reduce the administrative burden, enhance the internal market and increase the availability of veterinary medicinal products, while guaranteeing the highest level of public and animal health and environmental protection;

(II) sets high standards of quality, safety and efficacy for veterinary medicinal products in order to meet common concerns as regards the protection of public and animal health and of the environment; and

(III) harmonizes the rules for the authorization of veterinary medicinal products and their placing on the Union market.

In order to ensure uniform conditions for the implementation of this Regulation, implementing powers are conferred on the Commission, which are to be exercised in accordance with Regulation (EU) No. 182/2011 of the European Parliament and of the Council.

The Veterinary Regulation entered into force on 28 January 2019, however it shall only apply starting with 28 January 2022 and shall be binding in its entirety and directly applicable in all Member States. Regulation (EU) 2019/6 was published in the Official Journal of the European Union L4 as of 7 January 2019.

Amendment of the EU medicinal products for human use legal framework

Regulation (EU) 2019/5 of the European Parliament and of the Council of 11 December 2018 (the "Regulation") entered into force on 28 January 2019. It amends Regulation (EC) No. 726/2004 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency ("Regulation 726/2004"), Regulation (EC) No. 1901/2006 on medicinal products for pediatric use and Directive 2001/83/EC on the Community code relating to medicinal products for human use.

As Regulation (EU) 2019/6 detailed above regulated the procedures applicable to the centralized marketing authorization of veterinary medicinal products, starting 28 January 2022, the parts of Regulation 726/2004 that relate to procedures covered by Regulation (EU) 2019/6 will be repealed.

Other main elements of change brought about by the Regulation, which are however applicable since 28 January 2019, are as follows:

(I) The core elements of the rules on marketing authorizations which are subject to specific obligations (specified in Commission Regulation (EC) No. 507/2006) are moved into Regulation 726/2004, while maintaining a delegation of powers that allows the Commission to supplement

Regulation 726/2004 by adjusting the procedures and provisions for granting and renewal of such marketing authorizations and by specifying the categories of medicinal products that fulfil such requirements;

(II) Consolidation of the system for the examination of applications for variations to the terms of marketing authorizations by moving its core elements into Directive 2001/83/EC and Regulation 726/2004, while maintaining in both acts a delegation of powers that allows the Commission to complement those core elements by laying down further necessary elements and to adapt this system to technical and scientific progress;

(III) Detailed rules concerning financial penalties for failure to comply with certain obligations laid down in Regulation 726/2004 and in Regulation (EC) No. 1901/2006 are specified in Commission Regulation (EC) No. 658/2007. Those rules are maintained, but in order to consolidate them, the core elements and the list specifying those obligations are moved into Regulation 726/2004, while maintaining a delegation of powers that allows the Commission to supplement Regulation 726/2004 by laying down procedures for imposing such financial penalties;

(IV) In order to ensure uniform conditions for the implementation of Regulation 726/2004 in relation to marketing authorizations for medicinal products for human use, implementing powers are conferred on the Commission. These powers will be exercised in accordance with Regulation (EU) No. 182/2011 of the European Parliament and of the Council.

Regulation (EU) 2019/5 was published in the Official Journal of the European Union L4 as of 7 January 2019.

BEYOND THE LAW

Artificial Stardust is created by Romanian researchers in Alexandru Ioan Cuza University

A team of researchers from the Alexandru Ioan Cuza University, Faculty of Physics in Iasi, has been creating stardust. And their effort has been recognized worldwide, as the results were published in the prestigious astrophysics journal Oxford University Press, "Monthly Notices of the Royal Astronomical Society", volume 481, no.2.

The scientists discovered the particles accidentally 3 years ago. The stardust made an appearance due to a special set of circumstances every scientist dreams of, known as „serendipity". Serendipity defines a tremendous discovery made by chance, while in searching for something totally different. Specialists then began to study the chemical complexity of the interstellar environment and today dozens of samples from different years are kept in the lab. It is considered unique in the world for it is deposited on the slides in normal conditions of temperature and pressure. In other laboratories in which it was obtained, either very high temperatures or very low pressures were used.

According to a video shared on the University's Facebook page, it takes six hours to make one milligram of artificial stardust. And it's "messy and chaotic," "fluffy," and of all sizes, "just as we would expect it to be in space."