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Legal News
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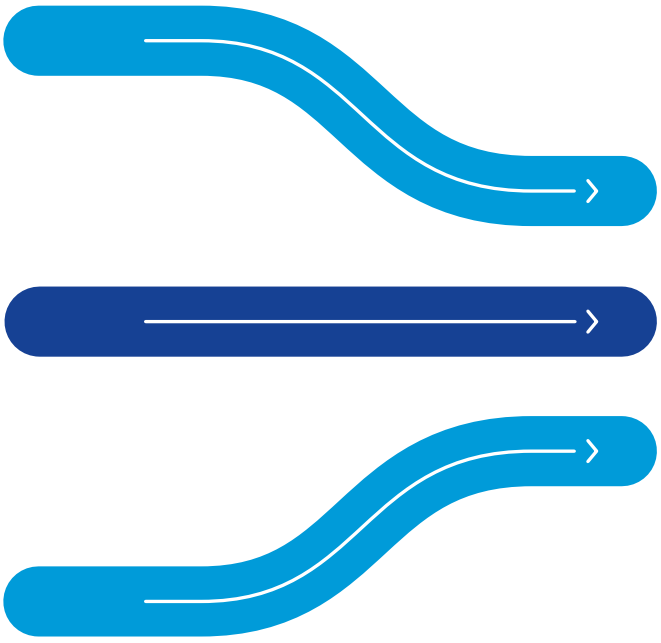
Central- and Eastern Europe



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Important changes to regulation of advertising for medical devices in the Czech Republic

On 26 May 2021, an amendment to the Advertisements Regulation Act came into force, introducing specific and detailed rules for advertisements for medical devices in the Czech Republic.

Aside from pharmaceuticals, medical devices and in-vitro diagnostics (IVD) are a commodity with direct impact on the health of individuals and the public at large.

Even so, the Czech Republic currently has no specific laws regulating advertising for medical devices, so that they may be advertised under the same rules which apply to regular products.

Change is afoot. Following the example of regulations in the field of advertising for pharmaceuticals, detailed and specific rules for advertisements will also be added for medical devices, both for advertising aimed at the broad general public and for advertising aimed at experts (i.e., those who may prescribe or issue medical devices, e.g. medical doctors). The new rules cover a broad range of activities, from advertising in the narrow sense (i.e., the wording and contents of ads) to handout of samples, visits by trade representatives at experts' offices, or sponsorship of scientific congresses and similar gatherings.

The amendment to the Act also introduces rules for advertising for what is known as consumer health products – i.e., products which are neither pharmaceuticals nor medical devices, but present themselves as such, a category in which one may find wearables such as smart watches which can monitor body functions, sporttesters, or various dietary supplements or cosmetics.

The amendment to the Advertisements Regulation Act will thus reverberate not only in the pharmaceutical sector, but also among businesses outside this particular market. All potential stakeholders are well advised to familiarize themselves with the new rules and to review their advertising campaigns, business practices, and promotional activities no later than on the day which marks the end of the 6-month transitional period after the effective date of the amendment.

In case of need, our law firm will gladly assist you with an analysis of your advertising campaigns.

Source: Act No. 90/2021, explanatory memorandum related to the bill for the Act

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Electronic breakthrough in the Polish National Court Register

The recent amendment to the National Court Register Act facilitates communication and document exchange with the register courts.

From 1 July 2021, the functioning of the National Court Register (PL: Krajowy Rejestr Sądowy) has changed. This is because a long-planned amendment to the National Court Register Act has come into force. From now on, both the registration and the change of data of entrepreneurs in the register will be made via the website https://prs.ms.gov.pl/ . What does it look like in practice?

Entrepreneurs must apply for entry or change in the register only in electronic form - paper applications will not be accepted. Now applicants must affix an electronic signature. The amendment also introduces adaptation of the electronic system of the National Court Register to the Central Repository of Electronic Extracts of Notarial Deeds (PL: Centralne Repozytorium Elektronicznych Wypisów Aktów Notarialnych). In consequence, applicants will no longer be required to file original notarial deeds with the register court. Applicants will also pay for their application directly through the portal where the application is filed. In addition, the portal will allow applicants to view registry files that were filed after the amendment came into force. Correspondence with the court will also be conducted electronically, which gives hope for acceleration of proceedings.

These changes, however, only concern entrepreneurs. Associations, other social and professional organizations, foundations and health care units can still apply to the National Court Register in both paper and electronic form.

Digitalization of these proceedings, although it may initially involve some chaos, will certainly accelerate and simplify the procedure for registering changes in the register of entrepreneurs. The amendment is the aftermath of Directive 2017/1132 of the European Parliament and of the Council (EU) of 14 June 2017, which establishes a system of interconnection of company registers.

Source: Act amending the Act on the National Court Register and certain other acts of 26 January 2018 (Journal of Laws of 2018, item 398)

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A new legal institution in Hungarian law: restructuring

Another lifebelt for Hungarian firms on the verge of insolvency

A new procedure has been adopted and entered into force on July 1st, 2022 to stabilize the financial situation of companies on the verge of insolvency. This transposed the EU Directive on Restructuring and Insolvency into the Hungarian legal system. Its aim is to keep a company afloat despite its financial difficulties and for the debtor company to adopt and implement a restructuring plan with creditors to prevent a possible bankruptcy or insolvency procedure.

The restructuring procedure has many similarities with the reorganization procedure, the subject of our previous newsletter. Although they have similar aims and will run in parallel for a period (July 1 2021 - December 31,2022), they have different rules. The reason is that reorganization can be initiated by a company facing imminent insolvency, whereas restructuring can be applied in the case of a probability of insolvency. There is currently no legal definition between the two concepts, and in the absence of case law, it can be concluded that the reorganization procedure is fast, urgent, and more binding, and that it is also aimed at more distressed companies. Accordingly, it is subject to stricter procedural rules and more stringent legal conditions.

To be noted, combining the procedures is not allowed, so the differences must be considered when deciding which is better for company survival.

The main difference between the two procedures is a moratorium, starting with its imposition. In the case of reorganization proceedings, this decision is the responsibility of the expert, and if the company is deemed fit to proceed successfully, the court will order a moratorium. The moratorium is therefore subject to the prior opinion of the expert of the National Reorganization Nonprofit Kft.

In contrast, in the case of restructuring, a moratorium is imposed by the court at the request of the debtor and can be general, covering all creditors, or limited, only for the creditors concerned. It may last up to 1 year and may be temporary. It is therefore up to the debtor to decide which creditors to negotiate with and who to involve in the procedure. Close judicial control is present throughout the

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procedure as the main element of the procedure, the restructuring plan, is also approved by the court.

Importantly, legal representation is mandatory for both procedures, so companies should consult their advisers before they start to decide which institution to use to help their distressed firm.

Source:

Act LXIV of 2021 - on restructuring and amending certain acts for harmonization purposes,

Government Decree 345/2021 (18.VI.) on reorganization and Act XLIX of 1991 on Bankruptcy Proceedings and Liquidation Proceedings and Act V of 2006 on Public Company Information, Company Registration and Winding-up Proceedings,

DIRECTIVE (EU) 2019/1023 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

Will there be a stronger European Health Union?

Lessons learned? The EU on its way to a new approach in pharmaceutical regulation. Feedback from CEE countries to the EU Strategy.

Many EU initiatives have seen the light of day in recent months to renew EU policy and regulation in the pharmaceutical sector. All of them will form bricks to build a stronger European Health Union.

Initiatives include, e.g.:

- to establish a new institution on EU levels – the Health Emergency Preparedness and Response Authority;
- to create a European Health Data Space;
- to adopt a Health Technology Assessment Regulation;
- to contribute to the European Pillar of Social Rights;
- to align the pharmaceutical sector to other EU projects.

In addition, at the end of 2020 the EU initiated the renewal of the Pharmaceutical Strategy for Europe, revising pharmaceutical legislation to address potential weaknesses with the following major goals:

- delivering for patients - unmet medical needs and unequal access to medicines for patients across the EU;
- a competitive and sound legislative framework to quickly respond to innovation and enabling digital transformation;
- enhancing resilience - securing supply of environmentally sustainable medicines and enhancing EU health crisis mechanisms.

The Pharmaceutical Strategy and the Combined Evaluation Roadmap/ Inception Impact Assessment draws conclusions not only from application of current EU pharmaceutical legal acts but also from issues experienced during COVID-19.

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Initial feedback from all interested persons was collected by the end of April 2021.

Different opinions were received from pharma associations and institutes of CEE countries with generally positive feedback to the initiatives as such.

However, many opinions stress the fact that inequalities in access to medicines and affordability will not be resolved solely by EU regulation since they also originate also from the size of markets, national regulations (especially pricing & reimbursement), national timelines and readiness of national health systems. This was stressed by the Romanian Association of International Pharmaceutical Producers, the Polish INFARMA, and the Lithuanian Free Market Institute.

The AIFP of the Czech Republic suggests that the legislative framework should allow policy adaptions at a later stage without the need to revise the whole legislation anew.

Suggestions from the lessons of COVID-19 include enhancing the process of resource allocation, reforming procurement, rationalizing stockpiling away from uncoordinated national stockpiling demands, and use of data from national databases due to the Falsified Medicines Directive.

High Court decision on letters of guarantee issued by a credit institution

Letter of guarantee issued by a credit institution - enforceable title only if it guarantees a credit agreement

At the request of the Bucharest Court, the High Court of Cassation and Justice Committee for resolution of certain questions of law ruled on the enforceability of a bank guarantee letter.

On 7 June 2021, the High Court ruled that a letter of guarantee issued by a credit institution is enforceable only if it is issued to guarantee a credit agreement.

This interpretation is to address ambiguous regulation regarding the enforceability of this personal guarantee, determined both by the current form of Emergency Ordinance No 99/2006 ("GEO 99/2006") which repealed Law No 58/1998 on banking activity ("Law no. 58/1998") and by the provisions of the Civil Code on personal guarantees.

In this context, a letter of guarantee issued by a credit institution will constitute an enforceable title only if it is issued to guarantee a credit agreement. This solution of the High Court is useful from several perspectives.

On one hand, this interpretation is a necessary reference point in relation to uneven practice in this area, generated by uncertainty concerning the character of a bank guarantee letter as an enforceable title. On the other hand, it establishes the object of the guarantee for the letter to constitute an enforceable title, which is a credit agreement.

Although this decision is binding on the court that requested the decision from the date of its ruling, of real interest are the considerations of the High Court, contained in its reasoning to be published no later than 30 days from the date of the ruling.

Thus, the decision will become binding from the date of publication in the Official Journal, no later than 15 days as of the date of the reasoning.

Source: Decision of the High Court of Cassation and Justice no. 43 in Case no. 643/1/2021, Law no. 287/2009 on the Civil Code, GEO no. 99/2006 on credit institutions and capital adequacy, Law no. 58/1998 on banking activity

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Innovations in the “Great Stone” Industrial Park

New business activities and subjects of the special regime, additional benefits for large residents, institutions of “English law”.

Presidential Edict No. 215 of 11 June 2021 „On amending presidential edicts” (hereinafter – “Edict”) updates the previous Presidential Edict No. 166 of 12 May 2017 “On improving the special legal regime of the China-Belarus “Great Stone” Industrial Park.

From now on, the list of core business activities of the “Great Stone” Industrial Park includes creating and developing industries in the fields of biopharmaceuticals, medical products, medical services, laboratory diagnostics, as well as the use of 5G technologies and artificial intelligence in all areas of the Park's activities.

In addition to the inclusion of medical services on the list of core business activities, the new rules introduce several specifics of its operation. Thus, if the Park Administration permits, residents can use unregistered medicines and medical devices as well as apply methods of supplying medical services that were not approved as established by legislation. Obtaining special permission (licence) is not required. However, residents must comply with statutory requirements related to premises, equipment, transport necessary for supplying services, hygienic requirements, personnel training, etc.

Some residents of the Park are granted special status. Thus, legal entities (individual entrepreneurs) located within the Park, registered as subjects of innovation activities and carrying out (or planning to carry out) innovation activity (in line with the Park’s aims) in the Park are entitled to the main benefits and preferential status for Park residents during the first two years of their activity. Moreover, some other legal entities which met criteria set forth by Edict are also entitled to benefits and preferential treatment for Park residents if the Council of Ministries of Belarus approves.

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Furthermore, additional benefits are introduced for entities implementing large investment projects involving investment of at least 50 million US dollars to be implemented within 5 years. Benefits include dividend tax at the rate of 0% for 10 years and simplification of some customs procedures for import of goods.

Institutions of “English law” are now also available for Park residents involved in innovation activity. From now on, they can sign convertible loan agreements between themselves and (or) with third parties, as well as agreements to grant an option to conclude an agreement and option agreements, including in relation to stocks and allotted portions of share capital.

The changes come into legal force from 17 September 2021.

Source: National legal internet portal of the Republic of Belarus (NLIP)
16.06.2021, 1/19719

Acquisition in Slovak Real Estate Law - NEW RULES!

Acquisition by prescription can be a practical means of acquiring the right of ownership or other rights, such as a right of way. However, the new rules are intended to avoid possible fraud in the process of acquisitive prescription.

Before every major real estate purchase, the investor checks whether the property is also in good legal condition, i.e., whether the seller is not only the owner according to the land register, but whether he can also prove flawless acquisition titles for a period of at least ten years. Ten years because this period corresponds to the length of the period of acquisition. However, the right of succession is also relevant for future acquisition of a property or even an easement, e.g., a right of way. If the owner of a property uses a right of way in good faith, even if his acquisition title to the right of way is shown to be defective, he can still acquire it by adverse possession. This is certainly important for real estate projects where defects in the title can be remedied by way of acquisitive prescription or where missing rights can be secured in this way. For example, if an investor finds that he does not have the right to use the road leading to his property, he may be able to acquire a right of way through the process of adverse possession. However, as of May 2021, the procedure leading to legally binding confirmation of a right of way will be significantly tightened. This is primarily intended to exclude possible cases of fraud. In the past, notaries who confirmed (notarised) seizure, were only satisfied with a declaration by the seizing party, often without examining the factual conditions of the seizure. Now, the court has to decide on seizure in a special procedure. The grantor must first prove the factual conditions - above all bona fide possession for 10 years.
If, in the opinion of the judge, these conditions are fulfilled, everyone concerned is given the opportunity to lodge an objection. Persons affected are those whose rights are registered in the land register and are affected by the adverse possession. Those who are not registered in the land register may also come forward (the court summons is published on the official notice board). Thus, the court is the final arbiter of the issue of adverse possession.

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Source: Act No. 161/2015 Coll. Slovak Code of Civil Procedure as amended.

Income tax in the case of cross-border posting of workers

In the case of a posting abroad, the first place of work is usually at the host company.

In no less than three recent decisions, the Federal Fiscal Court (Bundesfinanzhof, BFH) ruled that the so-called "first place of employment", which is decisive for income tax purposes, in the case of a posting abroad is the fixed place of business of the host company where the employee works for the duration of the posting.

It is not uncommon for employees (also within a company group) to work for a certain period of time at (sister) companies abroad by way of a posting of employees. As a rule, the employment relationship with the home company is "suspended" for the duration of the posting. From the perspective of income tax law, the question arises in these cases as to where the so-called "first place of employment" is located in relation to the foreign activity. This is important for assessing the extent to which the posted employee can deduct the costs, e.g. for his home abroad or the flights between his home country and place of work, as income-related expenses.

The "first place of employment" is defined in section 9(4) sentence 1 EStG as the fixed place of business of the employer, an affiliated company or a third party designated by the employer to which the employee is permanently assigned.

In the cases decided by the BFH, the judges assumed that the employee was "permanently assigned" to the foreign company on the basis of an employment contract with the foreign company that was limited to a period of 3 years. The suspended employment relationship in Germany did not change this assessment, nor did the fact that the employee had kept his home in Germany during the posting.

The ruling shows that even in the case of a temporary posting, special attention should be paid to the tax consequences of the posting in order to avoid unpleasant surprises. A "first place of employment" is not impossible in this context; however, caution is required in the contractual and actual structuring of the posting.

Source: BFH, decision of 17.12.2020 - VI R 21/18; VI R 22/18 and VI R 23/18

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