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Legal News in e-Commerce, Blockchain and FinTech

E-commerce has been subject to updates in relation to the development of a new wave of EU legislation as part of the "New Consumer Policy", which governs the issue of online offer rankings and comparison or the issue of dual product quality. The objective of the new draft directive is to make the operation of on-line markets and on-line comparison services more transparent.

EU Parliament Adopts Two Directives Regulating E-Commerce

In March, we informed you of the legislative processes relating to the directive on certain aspects of contracts for the sale of goods and the directive on certain aspects of contracts for the provision of digital contents and digital services. The directives primarily aim to limit the obstacles for cross-border shopping in relation to consumers. These directives were adopted by the Parliament and Council of the EU in the debated wording and are expected to be signed.

EU member states will have two years to make appropriate adjustments to their respective national legislations to ensure compliance with the directive.

EU Parliament and Commission have Decided to Strengthen Consumer Rights

In April, the European Parliament approved new consumer protection rules whose objective is primarily to amend the issue of online offer rankings and comparison and the issue of dual product quality. This directive represents another step of the European Union in implementing the plan referred to as the "New Consumer Policy".

The new draft directive primarily aims to increase the transparency of how online marketplaces and comparison services work in respect of customers (consumers). Going forward, they should namely publish the parameters that determine the ranking of the specific offers posted by them or the ranking in which the offers are displayed in the customer's (consumer's) search engine. The legislation should also ensure that customers are appropriately informed about the entity from which they make the purchase, ie whether they purchase products or services directly from the operator of the online marketplace, from a trader (business) or from a private entity, thereby also making sure that the customer (consumer) is sufficiently informed about his or her rights prior to making the purchase.

The new draft directive also addresses the issue of dual product quality, which refers to situations where the business offers goods under the same brand that have substantially different composition or characteristics in different member states. According to the existing draft directive, such actions should extend the existing definition of unfair commercial practices and should be banned, with the exception of situations when such actions on the business's (trader's) part would be justified by objective factors (such as the availability and seasonality of foodstuffs). However, the existing draft may give rise to ambiguities in interpreting the term "considerable difference".

A large-scale violation of the consumer protection legal regulations in multiple member states could, based on the new rules, be subject to a fine of up to 4% of the business's (trader's) annual turnover for the prior year. If the information about the business's (trader's) turnover is unknown, the maximum penalty could amount to EUR 2,000,000.

The draft directive will now be subject to a vote by the EU Council. If the directive is approved in the existing wording, member states will have 24 months to transpose it to national legislation.

To learn more about the issue, visit the website of the European Commission.

Václav Filip
vfilip@deloittece.com

Ján Kuklinca
jkuklinca@deloittece.com

Matúš Tutko
mtutko@deloittece.com

Regulation of Research and Development Tax Deductions: Victory of Substance over Form

The outcome of development projects is always uncertain. Therefore, it is important to provide various forms of aid for businesses to embark on these uncertain projects. From the tax perspective, this primarily includes the possibility of treating research and development costs as a tax-deductible item. However, in respect of this form of aid, some businesses have so far objected that the regulation itself is uncertain. All this has changed with the amended Income Taxes Act that significantly revises the manner of regulating deductions for promoting research and development.

One example for all. The existing treatment of the deduction for promoting research and development ("R&D") required that the written project of the R&D in the pipeline be prepared and signed prior to the commencement of its implementation. In relation to this requirement, long disputes were held as to when exactly the implementation of the development project commences and, therefore, when the written document has to be signed. Utilised deductions were contested, for example by stating that the research and development project should have been signed by the business prior to negotiating the contractual terms with the customer or prior to any preparatory activities. Paradoxically, authorities did not examine which projects were of an R&D nature and, as such, should have been supported, but whether the statutory executive did not sign the project a couple of days later. These disputes were terminated by a case represented by Deloitte Legal's attorneys-at-law and held before the Supreme Administrative Court. The Court upheld that the project commences as late as when it is duly approved and signed. While court rulings have established the practice in enforcing unclear legal provisions, they have unfortunately not encompassed all those of key importance.

Will the amended act help?

Since as early as 1 April 2019, new rules for utilising R&D tax deductions have been in effect. The amendment to the Income Taxes Act was made in response to the recommendations of the task force set up under the leadership of the Research, Development and Innovations Council in which Deloitte was also involved. One of the objectives of the amendment is to remove the uncertainty experienced by payers utilising the R&D tax deduction. A major development is primarily the fact that it will be newly sufficient to merely inform the tax authority in advance of the intention of utilising the R&D deduction. The full project documentation will need to be prepared before the deadline for filing an ordinary tax return expires. This method of regulation is a much better reflection of how development projects are carried out by businesses. In fact, businesses generally do not design development projects without carrying them out, but flexibly respond to the present market situation to always be one step ahead. Payers will now not need to worry about preparing formally correct project documentation in advance or otherwise risk losing this tax relief. As a result, businesses will be able to concentrate on the technical implementation of the project so that it has the most certain outcome possible.

Deloitte Legal has succeeded in research and development tax deduction disputes

Deloitte Legal's tax litigation team has succeeded in all disputes relating to research and development tax deductions. The possibility of deducting the costs of development activities from the tax base constitutes substantial tax support. However, in practice, businesses face ambiguous rules for its utilisation. Deloitte has represented several clients in this regard and led their cases to successful conclusion. As a result, businesses were not only refunded unlawful additionally assessed tax along with interest on the tax administrator's unlawful actions for court disputes spanning years, but the rules for utilising the deduction in subsequent years have also been clarified. If you would like to know more, contact Jiřina Procházková, an attorney-at-law, at jprochazkova@deloittece.com.

Jiřina Procházková
jprochazkova@deloittece.com

Amendment to the Act on Medicinal Products – Another Step towards the Digitisation of the Health Service and a New Obligation to Report the Prices of Medicinal Products

The Chamber of Deputies is currently debating, as Parliamentary Print No. 302, Amendment to Act No. 378/2007 Coll., on Medicinal Products and Amendments to Some Relating Acts, as amended (the "Medicinal Products Act"). On 9 May 2019, the Medicinal Products Act passed the second reading in the Chamber of Deputies, with proposed amendments sent to deputies on 10 May 2019. The third reading of the amendment is currently scheduled for the 30th Chamber of Deputies' session, ie on 28 May 2019.

Patient's Pharmaceutical Record

Since January 2018, physicians have been obliged (with the exception of specific cases) to issue prescriptions in the electronic form. Nevertheless, the existing wording of the Medicinal Products Act makes it impossible to further use the information on the medicinal products prescribed and dispensed in providing health services to the patient. However, this information may, in fact, be of crucial importance for the attending physician as well as the pharmacist dispensing the prescribed medicinal products so that possible contraindications of individual prescribed pharmaceuticals can be identified in time and the patient's safety ensured.

Thanks to the pharmaceutical record, physicians and pharmacists should be provided, in the Central Repository of Electronic Prescriptions, with access to information not only about all prescribed medicinal products, but also about those actually dispensed. Physicians (registering or attending to the patient, or emergency service physicians) will have access to pharmacotherapy information through the pharmaceutical record only in relation to the provision of health services. Similar will apply to pharmacists, who will be able to consult the pharmaceutical record in dispensing a medicinal product (based on a valid and as yet fully unutilised e-prescription) or during personal consultations with the patient (by entering the number of the patient's identity card or passport in the eRecept system). Restrictions to the range of authorised persons should prevent the threat of the data contained in the pharmaceutical record being leaked or abused.

The Patient Need not Agree

Nevertheless, the patient will be able to express their opposition to having their record accessed at any time (referred to as the "opt-out"). The patient may revoke their opposition at any time (ie, make it possible to have their pharmaceutical record accessed within the boundaries of law), or only give their consent to having their record accessed to specific physicians or pharmacists (referred to as the "selective consent").

Physicians and pharmacists will be able to view the information about the patient's medication stored in the eRecept system under the above-described conditions for a period of up to one year from the date on which the relevant record was created. However, in our view, it would be appropriate if, at least under certain conditions, the physician had a comprehensive knowledge of the patient's entire pharmacological history.

Obligation to Report Information about the Price of the Medicinal Product

Furthermore, the amendment extends the reporting duty of the holders of marketing authorisation under Section 33 of the Medicinal Products Act. At present, marketing authorisation holders are already obliged to report, to the State Institute for Drug Control (the "**Institute**"), among others, information on the volume of the supplies of medicinal products introduced on the Czech market, including the identification of medicinal products and information as to whether they were supplied to a distributor or a pharmacy. Marketing authorisation holders will also be newly obliged to inform the Institute of the price of the medicinal product in the report.

By analogy, the amendment also revises Sections 77 and 82 of the Medicinal Products Act, which stipulate the scope of compulsory reports in respect of distributors and pharmacies. These entities will also be newly obliged as part of the reporting duty to inform the Institute of the prices of medicinal products. In respect of distributors, this will apply to the price for which the medicinal product was supplied to another distributor in the distribution chain or pharmacy. In respect of pharmacies, this will apply to the prices for which the medicinal product was dispensed.

The sanction for violating the reporting duty, which also newly includes the duty to report information on the prices of medicinal products, may amount to a maximum of CZK 20 million in respect of the violation by a marketing authorisation holder, and a maximum of CZK 5 million in respect of the violation by a distributor.

Effectiveness

The amended act is likely to become effective on the first day of the second calendar month following the promulgation date, ie on 1 July 2019 at the earliest (the effective date is also subject to proposed amendments, both on the part of the Constitutional Committee and deputies).

Proposed Amendments

A series of major amendments have been proposed in respect of the bill.

- Two of the proposed amendments include a change in the system of the patient's presumed agreement (opt-out) to the opt-in system. Therefore, the concept is quite the reverse, whereby it would only be possible to access the information in the patient's record based on the patient's previous consent, namely owing to the sensitivity of medication data and indirectly the patient's health condition. Another major argument in favour of the opt-in concept is the association of certain chronic conditions with a high degree of social stigmatisation. Patient organisations repeatedly record breaches of the confidentiality obligation in respect of these conditions, which often leads to the patient's further social ostracism.
- Another amendment has been proposed by Patrik Nacher, who proposes that the regulation governing the mail order dispensation of prescription-only medicinal products be revised with effect from January 2021. Therefore, it should newly be possible to dispense not only over-the-counter (so called OTC) medicine, but also prescription-only medicine.
- Based on the amendment proposed by a group of deputies headed by Petr Pávek, Section 77 (1) (h) of the Medicinal Products Act, the purpose of which is to ensure the availability of medicinal products for patients, should be revised. At present, the provision stipulates that distributors must ensure the delivery of a medicinal product following the pharmacy's request no later than within two working days, with the pharmacy being able to contact any distributor regardless of whether the distributor trades with the medicinal product or not. Subsequently, marketing authorisation holders are obliged to supply the medicinal product to the distributor in the volume corresponding to the size of its market share. The amendment restricts the distributor's right to call on the marketing authorisation holder to supply the medicinal product if the availability is not ensured by the marketing authorisation holder otherwise. Subsequently, the distributor is obliged to supply the medicinal products supplied to it by the marketing authorisation holder based on a call only to a pharmacy (or a physician in the event of vaccines). The amendment additionally abolishes considering distributors' market shares, also in view of non-compliance with competition law mentioned multiple times in the past.
- The affected provision is also addressed by another amendment, this time proposed by the government, which, besides the abolition of the section relating to market shares, proposes that the obligation to supply requested medicinal products within two days should only apply to the distributors that will voluntarily assume the obligation in assuming the public service obligation based on a written statement to the marketing authorisation holder. Furthermore, the amendment introduces a protected distribution system as part of which the distributor, that has voluntarily assumed the duty, is obliged to maintain stocks of inventory in such amounts as to be able to supply the necessary medicinal products to a pharmacy within two working days.

Deloitte's Note: the above-outlined proposed amendments relating to the obligatory system of supplies merely confirm the shortcomings of the existing legislation which the experts from among the public have pointed out since the very beginning of its existence. Therefore, a systemic change may be expected in respect of the emergency supply system in the near future.

- According to the amendment proposed by deputy Kamal Farhan, the Institute should newly be authorised to also provide information relating to the certificates that it issues under Section 81a (1) of the Medicinal Products Act for access to the eRecept system to other bodies within the departmental scope of authority of the Ministry of Health (including the Czech Social Security Administration for the purposes of verifying the identity of attending physicians in the eNeschopenka or "e-Sick Leave" system) that will also be able to use the certificate to access and use the services and systems established or managed by departmental organisations.
- Furthermore, the amendment proposed by Věra Adámková recommends revising the regulation on food supplement advertising, which will have to contain an explicit and legible caution to consult the consumption of food supplements with a physician or a pharmacist. At the same time, the amendment should abolish the liability of advertising agents for the contents of advertising, given that they do not have the necessary specialised qualifications as opposed to ordering parties and processors.
- The amendment proposed by deputy Tomáš Vymazal addresses the price regulation of cannabis-containing medicinal products. The objective of the proposal is for individually prepared medicinal products containing cannabis to be fully covered for Czech patients, regardless of the unavailability, if applicable, of Czech cannabis and the necessity to procure cannabis through cross-border supplies. In this context, it is proposed that the method of determining the maximum price of the medicinal products be revised; however, from the perspective of pricing and coverage, this seems to be non-systemic.

Tereza Davidová
tdavidova@deloittece.com

Nikola Havlíková
nhavlikova@deloittece.com

Contacts

If you are interested in obtaining additional information regarding the services provided by Deloitte Czech Republic, please contact our legal specialists:

Deloitte Legal s. r. o
Churchill I
Italská 2581/67
120 00 Prague 2 – Vinohrady
Czech Republic

Tel.: +420 246 042 100
www.deloittelegal.cz
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