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CONTACTS
AN ASSESSING DOCTOR AS AN EMPLOYEE OF AN OCCUPATIONAL MEDICINE SERVICES PROVIDER?

As the transitional period in which employers are not required to comply with the new Specific Medical Services Act draws nearer, the concerns of some employers and occupational medicine services providers are growing over how to set correct rules for their collaboration in assessing the state of health of current and potential employees. Some of the related issues are addressed in this article.

Although the transitional provisions of Act No. 373/2011 Sb., on Specific Medical Services (the “Medical Services Act”), state that occupational medicine services may be provided in compliance with existing laws, this possibility will be lost by employers with effect from 1 April 2013. The deadline draws nearer while a great number of employers are faced with certain ambiguities arising from the new rules in the Medical Services Act.

One of the issues currently addressed by employers is the provision of occupational medicine services (“OMS”) by means of an agreement made between an employer and an occupational medicine services provider (i.e., such occupational medicine services where the report of an employee’s registering doctor is not sufficient). Is the employer required to contract a sole provider of occupational medicine to provide all OMS to the employer? And is the OMS provider required to ensure OMS via a sole provider (on the contrary, it assumes such services to be provided by several providers), it can be implied that the employer may arrange for the OMS be provided by several OMS providers. This is particularly practical for employers that have a large number of employees or workplaces located in different parts of the country.

In addition, there are no express provisions in the Medical Services Act regarding the possibility of an OMS provider to transfer its obligations arising from the agreement with the employer to another OMS provider by means of an agreement. Again, the general principle of law will apply, stipulating that whatever is not prohibited is permitted, and will be applied in practice. The Medical Services Act does not prescribe under which contract the OMS provider that has no employment contract with the employer is to examine the employees’ health condition. It is very easy to say that the contract between the two providers can be a commercial contract but the answer to this question is not that simple, because the provisions of the Labour Code (Act No. 262/2006 Sb., as amended) must be taken into account as well.

If the subcontractor of an OMS provider contracted by the employer is an individual (a doctor assessing a patient’s state of health), it is inevitable to avoid the relationship between the two providers being considered what is known as a ‘švarcsystém’, where work is performed under a commercial law contract instead of an employment agreement.

The Labour Code stipulates that employment may solely be performed in an employment relationship. A breach of this statutory obligation involves a risk of high penalties imposed by the Labour Inspection on the employer (in this case, the OMS provider performing OMS under an agreement with the employer) and the employee (the OMS subcontractor – the assessing doctor). The reason why the performance of an assessing doctor’s activities could be, in theory, considered employment is the fact that an assessing doctor performs his job solely in person and according to the instructions of the OMS provider, as employees are examined within the scope stipulated by the provider. The activities of an assessing physician accomplish some of the fundamental elements of employment (personal performance of the work by the employee according to the employer’s instructions). OMS providers who wish to delegate, under an agreement, some of their activities to assessing doctors that are not their employees are concerned that such an arrangement would be considered a ‘švarcsystém’. However, we are of the opinion that such concerns can be quite easily dispelled.

In general, we can state that if other elements are not accomplished and the assessing doctor performs his activity on his own behalf and responsibility (as the holder of a licence to provide medical services), at his own expense (using his own equipment and employing a nurse), outside the workplace of the OMS provider for whom the activity is performed (i.e., in his own office), during hours determined by him (not following the working hours determined by the OMS provider), and in particular is not directly organisationally subordinated to the OMS provider, such cooperation is rather unlikely to be considered as a ‘švarcsystém’.
It should be pointed out that the determination whether an assessing doctor’s activity can be considered employment always depends on the specific terms of the cooperation. Nevertheless, we can state that, in practice, OMS providers will definitely not be forced to provide OMS to employers only via their employees. Especially considering the amount of penalties applicable to a ‘švarcsystém’, it is advisable that the OMS providers pay special attention to and establish the contractual framework for collaboration with assessing physicians that will act as subcontractors for such activities, so that the above-described elements of employment are not accomplished and everything is done in compliance with the law. This means particularly Article 10 of the International Labour Organisation’s Occupational Health Services Convention No. 161 (Czech Decree No. 145/1988 Sb.) that requires that occupational health services be fully professionally independent from employers, and Section 54 (2) of the Medical Services Act, under which occupational medicine services may only be provided based on a contractual relationship between the employer and the service provider.

In conclusion, we should briefly mention that a motion to amend the amendment to the Specific Medical Services Act (chamber print no. 807) has been brought forward recently that is to permit employers licensed to provide medical services under the Medical Services Act in the a field under Section 54 (1) (a) or (b) to provide occupational medicine services for work performance in their workplaces via:

a) a doctor having specialised qualification in occupational medicine or specialised qualification in general medicine;

b) other healthcare workers participating in the provision of occupational medicine services;

with whom the employer has entered into an employment or similar relationship, provided that the employer is required to ensure the professional independence of the employees in points (a) and (b).

From the perspective of de lege ferenda, employers may provide occupational medicine services via their employees. Nevertheless, it is hard to imagine a scheme in which employers ensure the professional independence of their employees in providing occupational medicine services working in practice.

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OTHER HEALTHCARE LAW AMENDMENTS PLANNED

What is new about the draft amendments to the Life Sciences laws we introduced you to in our previous issues of Pharma News? And are there any other amendments being prepared by law-makers? The most interesting information is summarised in the following article.

The previous issues of our Pharma News presented several draft amendments and new regulations that would probably deserve amendment or the adoption of a statutory instrument due to their problematic application in practice. What progress has been made in this respect in the meantime? And what are the Life Sciences issues currently being discussed by the Parliament or the Ministry of Health?

Re-registration of medical facilities

The January Legal News highlighted the ambiguities of the transitional provisions of Act No. 372/2011 Sb., on Healthcare Services, which deal with the essential elements of applications for a licence to provide healthcare services submitted by healthcare providers that are registered under existing laws. However, it is now becoming obvious from guidance notes No. ZD15/2012 published by the Health Ministry that the re-registration will be a mere formality for non-state healthcare facilities and administrative authorities will only require simply the filling in of details in the application without the necessity to submit any other documents. The re-registration is to be requested of non-state healthcare facilities by 1 January 2013.

Amendment to the Pharmaceuticals Act

In April of this year, Legal News presented the intention of the Health Ministry to bring forward an amendment to Act No. 378/2007 Sb., on Pharmaceuticals. The amendment is to prevent customers who acquire medicines as pharmacy operators from distributing the medicines further without holding a licence to distribute pharmaceuticals. The government-proposed amendment was tabled in the Chamber of Deputies and ordered to be discussed by the Healthcare Committee as chamber print no. 783. Although it was to be discussed by the Chamber of Deputies in September, the proposal has been removed from the agenda of the meeting as not discussable.

The aim of the proposed amendment is also to ensure better control of counterfeit medicines and their adverse effects.

Amendment to the Advertising Regulation Act

The same destiny has so far awaited the amendment to Act No. 40/1995 Sb., on Advertising Regulation. The amendment is to introduce a ban on advertising human pharmaceuticals in the form of contest, lottery or similar competition consisting in the number of prescribed, consumed or dispensed pharmaceuticals, and a ban on providing, offering or promising bonuses in connection with dispensing prescription pharmaceuticals covered by public health insurance; in addition, this amendment is also to impose stricter rules that apply to sponsored meetings and congresses of medical professionals. Even this proposal (published as chamber print no. 761) has not been put on the agenda of the September meeting of the Chamber of Deputies and will not be discussed until the end of October at the earliest.

Mandatory medical examinations for new employees

The amendment to Act No. 373/2011 Sb., on Specific Healthcare Services (chamber print no. 752), which is to result in removing altogether the obligation of employers to require all new employees to undergo a medical examination, including those that are to work under an agreement to perform work (in Czech dohoda o práce) or agreement to complete a job (dohoda o provedení práce), passed its first reading in the Chamber of Deputies. As we reported in the June issue of our Pharma News, the obligation to send all employees before the commencement...
of their employment (or a similar relationship established by agreements for work outside employment) to entrance medical checks irrespective of the scope and nature of their work and subject to the penalty that such employee be considered unfit for work, has placed an excessive burden on employers in practice (or more precisely, will place an excessive burden when the transitional period will expire on 1 April 2013 during which employers are permitted to proceed in compliance with the existing laws). The proposal is now to be discussed by the Healthcare Committee.

At the same time, the Chamber of Deputies has been presented with a parallel draft amendment (chamber print no. 807) that is to limit the mandatory medical checks for those working under outside employment agreements. The obligation would thus only apply to employers where job applicants are to perform work classified as hazardous.

**University hospitals**

The amendment to the University Hospitals Act, which is to introduce a new legal form of university hospital into Czech law and whose principles were presented in the June issue, has passed the inter-ministry commenting procedure and is to be discussed in the Chamber of Deputies once the comments are incorporated.

**Amendment to the Paramedic Professions Act**

The Health Ministry has published a bill on the conditions of obtaining, acknowledging and recognising qualifications for paramedic professions and activities related to the provision of healthcare that is to replace the existing Act No. 96/2004 Sb., on Paramedic Professions. The bill has been published beyond the scope of the prescribed legislative procedure and made available for comments by the general public. Therefore, it can be assumed that the new law could reflect the requirements of the paramedic staff itself and better suit the application practice requirements.
On 28 September 2012, the National Council of the Slovak Republic was delivered a governmental draft amendment to the Act on the Scope and Conditions of Coverage of Medicinal Products, Medical Devices and Dietary Food via Public Health Insurance and on the Amendment and Supplement to Certain Acts, and amending and supplementing the Act of the National Council of the Slovak Republic No. 145/1995 Coll. on Administrative Fees, as amended (the “Amendment”). The Amendment is proposed to come into force from 1 January 2013.

The aim of the Amendment is to introduce in the Slovak Republic a new, and according to the Slovak Ministry of Health, also a more fair method of setting medicinal product prices, which would reflect price changes in other EU Member States and exchange rate changes in such a way so that the prices for medicinal products, medical devices and dietary food are not higher than an average of the three lowest prices within the EU. The current legislation stipulates that a medicinal product price set by a manufacturer or an importer may not exceed the second lowest medicinal product price among officially set product prices in other EU Member States.

However, the legislator’s intention is that the prices for medicinal products, medical devices and dietary food continue to remain at one of the lowest levels within the European Union also after the Amendment is adopted.

As the explanatory report to the Amendment implies, the medicinal products designated for mandatory vaccination are excluded from a special payment method, whereby the status applicable before Act No. 363/2011 Coll. came into force is restored.

The Amendment intends to specify the individual processes in more detail, simplify them, and eliminate administrative demands in such a way that it clarifies primarily the provisions regulating the payment of administrative fees for applications filed under the Act.

Kamila Turčanová,
Senior Associate
On 28 September 2012, the National Council of the Slovak Republic was delivered a governmental draft amendment to the Act on Medicinal Products and Medical Devices and on Amendment and Supplement to Certain Acts, prepared by the Ministry of Health of the Slovak Republic (the “Amendment”). The Amendment is proposed to come into force from 2 January 2013, except for certain special provisions that will come into force later.

The purpose of the Amendment is to transpose Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011, amending Directive 2001/83/EC on the Community code relating to medicinal products for human use (the “Directive”), as regards the prevention of the entry into the legal supply chain of falsified medicinal products, and to also make stricter the requirements for all the entities handling medicinal products for human use, in particular, for medicinal product manufacturing authorisation holders and medicinal product wholesale distribution authorisation holders.

Supervision Over and Limitation on the Export of Medicinal Products for Human Use

A significant change brought by the Amendment relates primarily to the supervision over medicinal products for human use, which is to be stricter after the Amendment is adopted.

As set out in the explanatory report to the Amendment, laying down specific rules for the supervision over medicinal products for human use is to achieve the protection of the public health system so as to limit, or prevent, adverse effects of medicinal products for human use introduced into the European Union market, as the safety of medicinal products for human use can currently be identified only after they are registered and introduced into the market.

Moreover, the Amendment imposes a burden only on wholesale distributors of medicinal products for human use, as medicinal product manufacturing authorisation holders are not imposed with such a duty, which, in our opinion, results in non-compliance with the requirement under the Directive to ensure control of the entire medicinal product distribution chain.

Professional Events for Medical Doctors and Healthcare Professionals

Another change proposed by the Amendment is the clarification of the definition of a ‘professional event’. The current wording of the Act on Medicinal Products and Medical Devices, (as well as the Code of Ethics of the Slovak Association of Research-Based Pharmaceutical Companies) clearly prohibits pharmaceutical companies from paying for spare time and relaxation activities for medical doctors and healthcare professionals but, however, does not precisely define what events are permitted and for what purpose.

The Slovak Association of Research-Based Pharmaceutical Companies itself supports the proposal to clarify the definition of a ‘professional event’, whereas it also supports a standard that at least 80% of a professional event must be of a non-promotional professional, educational and scientific nature. The remaining 20% may include accompanying events at which promotion is permitted to the specified extent.

Based on the foregoing, the Amendment also defines a ‘professional event’ based on the regulation of marketing activities of the entities involved in the medicinal product chain. The supplemented definition
aims at clarifying the activities that may be performed by individual entities set out in this Act. The definition of a ‘professional event’ only relates to professional, scientific or educational events that are designed exclusively for healthcare professionals, which may also include accompanying activities permitted by the Act on Promotion and their time frame may not exceed 20% of the total time frame of the professional event.

Omitting a So-Called ‘Bonus Fidelity System’

There are also proposed changes in providing pharmaceutical care, of which the most important is a proposal to omit the bonus fidelity system, i.e., the right of the holder of the authorisation to provide pharmaceutical care to grant or promise the patients discounts, benefits or a complex of discounts and benefits.

The Amendment is restoring the ban on the bonus fidelity system in public pharmacies, the aim of which is to remove the practices leading to an increased consumption of medicinal products, including medicinal products that may be dispensed without a prescription, so-called ‘over-the-counter’ medicinal products. In this respect, the explanatory report to the Amendment only gives a brief explanation implying that under medical rules, any method of promoting the use of medicinal products, mainly by making use of marketing practices, is inadmissible. The explanatory report further states that the bonus fidelity systems have no place in the current system because the Act prohibits such marketing activities overall; the only exemption where such marketing activities are currently permitted by the Act are the bonus fidelity systems applied in public pharmacies aimed at just the most vulnerable group of citizens, i.e., the patients. The objective of this Amendment is thus to also exclude this last exemption from the ban on promotion in the sale of medicinal products.

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Havel, Holásek & Partners, attorneys-at-law, based in Prague, with offices in Brno, Ostrava and Bratislava, with more than 140 lawyers and a total staff of more than 400 employees, including 130 employees of the cooperating collection agency Cash Collectors, is the largest Czech-Slovak law firm. The firm currently provides services to approximately 700 clients, more than 30 of which have been ranked as Czech Top 100 companies; approximately 80 rank among the Fortune 500. Based on the total number of awards and nominations in the official Law Firm of the Year competition, Havel, Holásek & Partners was the most successful Czech law firm in the last three years. This year, the firm was awarded the prestigious Who's Who Legal Award and was ranked the best law firm in the Czech Republic of the year 2011, and was also ranked the No. 1 local law firm in the overall ratings published by Practical Law Company. Furthermore, Havel, Holásek & Partners was awarded an ILO Client Choice Award 2010 by International Law Office (ILO), which named it the best-rated law firm by clients in the Czech Republic. Our lawyers are regularly cited as leading or recommended specialists by renowned international rating publications, such as PLC Cross-border, European Legal 500, Chambers Global Guide, European Legal Experts, Global Law Experts, and IFLR 1000, all of which have cited Havel, Holásek & Partners as one of the best law firms for transactions carried out in the Czech Republic in the areas of mergers and acquisitions, corporate and commercial law, banking and finance, capital markets, insolvency and restructuring, real estate and construction law, labour law and dispute resolution.