FORGÓ, VARGA & PARTNERS
LAW FIRM

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FORGÓ, VARGA & PARTNERS LAW FIRM

Introduction

Having advised for pharmaceutical companies extensively for many years, in 2004 we decided to set up a dedicated practice line for legal issues associated with the pharmaceutical industry. The practice is headed by partner Zoltán Forgó, support is provided on IP matters by partner Gábor Damjanovic.

Our practice line provides the following services:

- pharmaceutical regulatory advice (advertisements, pricing, registration including the EU law aspects);
- constitutional review of legal rules before the Constitutional Court;
- unfair trade practices (procedures before the Competition Authority, the Consumer Protection Authority and the National Institute of Pharmacy);
- Mergers & Acquisitions in the pharmaceutical industry, including merger control procedures;
- IP matters.

In order to mark our determination to the practice line, we decided to issue Newsletters on various legal issues of the pharmaceutical industry.

This issue covers the recent ruling of the Hungarian Constitutional Court on the Drug Economic Act. The ruling covered several payment obligations of the various players of the pharmaceutical industry. Most importantly, the ruling cancelled the special tax on sales agents, whereas the other payment obligations remained in place.

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Disclaimer

The content of this Newsletter is intended to highlight issues and not to provide a comprehensive analysis, neither should it be considered as legal advice.

The ruling of the Constitutional Court no 1152/B/2006 on the petitions related to the Drug Economic Act

The Act CXVIII of 2006 on the general rules of safe and cost-effective supply of medicinal products and therapeutic equipment and the distribution of medicinal products ("Drug Economic Act" or „Act"), passed by the Hungarian Parliament on 20 November 2006, gave rise to fierce debates among the players of the pharmaceutical industry. Therefore, it was not surprising that numerous constitutional reviews were initiated before the Constitutional Court regarding the often-criticized provision of "pharmacy liberalisation" and the various payment obligations, introduced by the Act.

The Constitutional Court assessed the petitions in two rulings. The first one, which addressed the petitions concerning the progressive termination of the restrictions regarding pharmacy establishment, the solidarity fee payable by the pharmacies and the possibility of distributing drugs outside pharmacies, was adopted in February 2008. In that ruling, the Constitutional Court dismissed all of the petitions; none of the challenged provisions were found unconstitutional.

Subsequently, the interested parties had to wait for months for the second ruling, which was only passed in June 2008. In this second ruling no 1152/B/2006 the Constitutional Court assessed the petitions, challenging the different payment obligations introduced by the Act.

In its ruling of June 2008 no 1152/B/2006, the Constitutional Court found unconstitutional the provisions which (i) prescribed a monthly payment obligation in connection with the employment of sales agents and (ii) exempted the marketing authorisation holders of generic products, in the year of admission to social security contribution, from the payment obligation to be paid if the Health Fund exceeds its target. The other petitions were dismissed. Below, we would like to briefly summarise and analyse this Constitutional Court ruling.

1. The attacked provisions of the Drug Economic Act

1.1 Payment obligations

In order to reduce social security spending on drugs, the Act introduced several new payment obligations for the industry players. From these payment obligations, the petitions assessed in the recent Constitutional Court ruling attacked three: (i) the 12 % payment obligation payable by the drug marketing authorization holders, (ii) the fee payable for the employment of sales agents, and (iii) the payment payable in case of the overrun of the Health Fund.

1.1.1 The 12 % payment obligation payable by the marketing authorization holders

Several petitioners challenged the provision, which introduced a payment obligation on the marketing authorisation holders of drugs (producers or importers) equal to the 12 % of the social security contribution taking into account the producer price of the drug.

According to the petitioners opinion, this payment obligation violates the *general and proportionate sharing of taxation*, as such payment obligation is not linked to the financial and income position of the taxpayers: the amount of the payment only depends on the trade figures of the drugs and the amount of the social security contribution and the marketing authorization holders do not have direct influence on these factors. Additionally, the Act in this respect discriminates without constitutional reason between the drug marketing authorization holders and the wholesale authorization holders, although both the activity of the marketing authorisation holders (producers and importers) and wholesale traders influence the volume of drugs sold. Therefore it violates the principle of the *prohibition on discrimination*.

1.1.2 The fee payable for the employment of sales agents

In order to discourage the promotion activity of manufacturers, the Act introduced a fee payable for the employment of sales agents visiting doctors and pharmacies. The amount of the fee was HUF 5,000,000 (app. EUR 21,280) for each drugs sales agents and HUF 1,000,000 (app. EUR 4,255) for sales agents of therapeutic equipment. From 1 January 2008, the fee was broken down by month: HUF 416,000 (app. EUR 1,770) for drugs sales agents and HUF 83,000 (app. EUR 353) for sales agents of therapeutic equipment.

This payment obligation, according to the opinion of the petitioners, also violates the principle of *general and proportionate sharing of taxation,* because it is not linked to the financial and income position of the taxpayers; this is a "quasi sanction" which aims to discourage the promotion. Additionally, the payment obligation is of confiscating nature, as the amount almost reaches the revenue originating from the promotion activity. Beyond the violation of the principle of general and proportionate sharing of taxation, the petitioners also referred to the violation of the *prohibition on discrimination,* as the payment obligation is only payable by the employers of sales agents, although numerous other market players' activity influence the trade figures of drugs. Furthermore, they also argued that the HUF 5,000,000 or 1,000,000 fee is practically makes the market entry impossible, therefore it violates the *right to enterprise*.

1.1.3 The payment payable in case of the overrun of the medicinal budget

The Act prescribes a payment obligation if the Health Fund exceeds its annual budget: up to an overrun of 9 % the overrun shall be financed by the State Health Fund and the marketing authorization holders jointly, while the extra expenditures beyond the 9 % overrun shall solely be borne by the marketing authorization holders, in proportion to the amount of the social security contribution paid for their products.

This provision, according to the opinion of the petitioners, violates the *principle of clarity of law*, as the Act does not define the basis and the rate of the payment obligation. It also violates the principle of *general and proportionate sharing of taxation,* because the payment obligation is not related to the income position, it may happen that a drug manufacturer has to make payment, although it did not contribute to the overrun of the Health Fund. Additionally, the payment obligation is *discriminative* because, in the year of admission to social security contribution, it only exempts from the payment obligation the manufacturers of generic products, but not the manufacturers of innovative products.

1.2 Price freezing

The Act makes the price freezing possible longer than previously, for a 2-year period, in order to avert or eliminate temporary disorder of the pharmaceutical market or to maintain its balance.

With respect to this provision, the petitioners have claimed that it violates the *principle of clarity of law* as the conditions for prize freezing are too vague, and disproportionately restricts the *freedom of contract*.

1.3 Rights to supervise promotion activity

In order to control the compliance with the rules of promotion, the Act provides broad rights to the Health Insurance Supervision: they may request anybody to hand over data or papers possessed by

them and any person must tolerate the search of his/her premises. These "investigation rights" have been attacked with reference to the *right to human dignity*, the *right to the integrity of private homes* and the *right to the protection of personal data*.

1.4 Ignoring the opinion procedure in the course of legislation

Several petitioners claimed the annulment of the whole Act with reference to the failure to consult the business federations and social organisation, which violated *legal security*.

1.5 Provisions regarding entry into force

The preparation time preceding the entry into force of the Act (30 days in general and 45 days for the payment obligations) have also been considered non sufficient. More petitioners have claimed the annulment of these provisions or the whole Act arguing that the brevity of the preparation time violates *legal security*.

2. The ruling of the Constitutional Court

2.1 Payment obligations

In connection with the payment obligations, as the first step, the Constitutional Court assessed whether they can be deemed as taxes. In this regard, the Constitutional Court, with reference to its previous rulings, took the position that there are no constitutional obstacles to prescribe payment obligations in acts other then the Act on State Budget, therefore the Constitutional Court considered the payment obligations as taxes.

In its ruling the Constitutional Court, in connection with s. 70/I of the Constitution prescribing the principle of *general and proportionate sharing of taxation ("All citizens of the Republic of Hungary have the obligation to contribute to public revenues on the basis of their income and wealth."),* made it clear that the state has large freedom regarding the selection of the economical resource forming the basis of the taxation provided that it meets the standard of proportionality, i.e. it is proportionate to the financial and income position of the citizens. It is important to note however, that this proportionality cannot be interpreted in a way that the amount of the tax shall be determined depending on the amount or value of the wealth or income, there is no obstacle to establish a *fixed amount tax*.

As regards the *extent of the tax*, the Constitutional Court pointed out that it only becomes unconstitutional if (i) it is discriminative or (ii) it reaches an extent where it obviously becomes disproportionate and unjustified. In the latter case we can talk about confiscatory taxes.

As regards the *economical resource* constituting the basis of the tax, the Constitutional Court quoted its ruling regarding the health contribution payable by self-employed entrepreneurs (which it found constitutional): it does not follow from the provision of the Constitution that the fact of employment or entrepreneurial activity cannot constitute the basis of tax payment. This approach was narrowed in its ruling concerning the "petty cash tax", where the Constitutional Court ruled that the non-acquired income cannot be taxed, it is against the principle of *general and proportionate sharing of taxation*, as in such case there is no connection between the tax and the income position of the taxpayer.

The Constitutional Court summarised the requirements of the legislation of taxes as follows:

(i) the taxes shall be proportionate to the financial and income position of the taxpayers;
(ii) the tax shall be proportionate to the tax paying ability of the taxpayers;
(iii) the tax shall be directly linked to the income or wealth on which the tax is imposed;

(iv) only the effectively acquired income or wealth is taxable.

In accordance with these aspects, the assessment of the Constitutional Court covered whether the payment obligations prescribed in the Act

(i) are proportionate to the financial and income position of the taxpayers;
(ii) violate fundamental rights, especially the prohibition on discrimination;
(iii) are of confiscatory nature.

2.1.1 The 12 % payment obligation payable by the marketing authorization holders

Firstly, the Constitutional Court assessed the *proportionality* of the 12 % payment obligation and established that the fact that the payment shall be made in proportion to the contribution and not the price of the drugs does not, in itself, result in the violation of the principle of general and proportionate sharing of taxation, as it does not follow from the provisions of the Constitution that only the turnover can be determined as the basis of the tax.

According to the opinion of the Constitutional Court, as a result of the fact that the payment obligation shall only be made after the drugs actually distributed in pharmacies, the *connection* with the financial and income position of the taxpayers *exists*. Furthermore, the payment obligation cannot be considered as *confiscatory*.

As regard *the prohibition on discrimination*, the Constitutional Court took the position that the marketing authorisation holders and the wholesale authorisation holders are industry players pursuing essentially different activity, therefore, with regard to the prohibition on discrimination, they do not belong to the same regulatory area. Consequently, the different extent of the payment obligation prescribed for the two groups does not raise the issue of discrimination.

As a result of the above, the Constitutional Court *dismissed* the petitions which claimed the annulment of the 12 % payment obligation.

2.1.2 The fee payable in connection with the employment of sales agents

In connection with the regulation of the drug promotion activity, the Constitutional Court stipulated that the regulatory role of the state may be stronger on the pharmaceutical market, the freedom of enterprise applies restrictively in this field. The legislator may restrict or prohibit, with constitutional means, the pursuing of certain activities (e.g. advertisement) or may establish conditions thereto.

As regards the constitutionality of the payment obligation, the Constitutional Court firstly assessed whether it is constitutional to prescribe a payment obligation, which shall be made *solely on the basis of the employment relationship*.

As it was stated generally, it does not follow from the principle of general and proportionate sharing of taxation that the fact of employment or undertaking, connected to the financial and income position, cannot constitute the basis of tax. The employer has an economical advantage (income) from the employment of the sales agents, which income can be taxed on the basis of s. 70/I. of the Constitution. According to the ruling of the Constitutional Court, in such case, the tax is *proportionate* to the income position of the taxpayer.

The fixed amount tax, which is not unknown in Hungary, is therefore, in itself, not contrary to the requirement of the general and proportionate sharing of taxation. However, the requirement that the payment obligation *shall be connected to the financial and income position of the taxpayers* is applicable also in this case. Therefore, actual work must be behind the employment relationship.

Conversely, if there is no actual work, the sales agent does not pursue its activity, the employer does not reach economic advantage, therefor there is no connection between the payment obligation and the financial and income position of the taxpayer.

Based on the above, the Constitutional Court came to the conclusion that, as the Act does not contain exemption provisions for cases when the employment relationship exists, but there is no promotion activity, the Act taxes an income actually not earned. Therefore, the *subject of the tax* is not the activity aiming to earn income, but the *relationship* itself. This violates s. 70/I of the Constitution, which stipulates the general and proportionate sharing of taxation; therefore, the Constitutional Court *annulled* this section of the Act.

Thereafter the Constitutional Court did not examine whether the violation of the further provisions of the Constitution cited by the petitioner can be established in connection with the contested regulation.

The question arises whether the Constitutional Court ruling results in a permanent situation or the Parliament, eliminating the mistakes criticised in the Constitutional Court ruling, introduces a similar special tax on the promotion activity.

Based on the thorough analysis of the Constitutional Court ruling, we believe that the Constitutional Court has not exclude the possibility of such solutions, as it declared that the employer has an economical advantage (income) from the activity of the sales agents, which can be taxed even with a fixed amount tax.

The Ministry of Health expressed similar view in their reaction to the Constitutional Court ruling: *"The Ministry would like to emphasize that only certain points of the detailed regulation of the sales agents' registration fee were found unconstitutional, not the establishment of the fee itself. The Ministry believes that the Constitutional Court ruling gave … unambiguous and clear guidance to make the contested provision constitutional. We plan to introduce the new regulation, supplemented with the constitutional requirements, to the autumn session of the Parliament"*.

2.1.3 The payment payable in case of the overrun of the Health Fund

The Constitutional Court set forth in a general level that the state is entitled to maximize the financial supply of a public task and the state, in the present case, chose the model of closed drug budget, which in itself does not raise constitutional problems.

According to s. 42 of the Act, if the total annual social security contribution actually paid after the drugs exceeds the annual budget, the extra expenditure up to a determined rate shall be borne by the State Health Fund and the marketing authorization holders jointly, while beyond that, it shall only be borne by the marketing authorisation holders. In connection with this rule, the Constitutional Court found that it is in compliance with the principle of *general and proportionate sharing of taxation* as it determines *how the payment obligation is split among the distributors,* that is it does not prescribe a "collective tax payment obligation".

The payment obligation does not violate the *principle of legal security*, as the legislator *determined it in advance when and what kind of extra expenditure* shall be financed by the marketing authorisation holders and how the obligation is split among each obligor. The violation of *clarity of law* can neither be established in connection with the regulation, as, according to the standpoint of the Constitutional Court, the regulation may be understood through legal interpretation.

The Act exempts from the payment obligation the marketing authorisation holders of generic drugs in the year of admission. However, according to the standpoint of the Constitutional Court, the distributors of generic and innovative drugs, in spite of the actual differences between generic and innovative drugs, constitute a *homogeneous group* from constitutional point of view. Therefore, the

different regulation within such a homogenous group is unconstitutional, it results in arbitrary discrimination, and as such violates the *prohibition on discrimination*. With regard to this, the Constitutional Court annulled the differentiation between the generic and innovative drugs. Subsequently, the second sentence of s. 42 (5) shall remain in effect with the following text: "*in case of products authorised for marketing as medicinal products, in the calendar year of admission for social security contribution, the marketing authorisation holder is not subject to the payment obligation arising from the joint risk bearing*."

The further petitions aiming at annulling s. 42 of the Act were *dismissed* by the Constitutional Court.

2.2 Price freezing

In respect of the regulation allowing price freeze, the Constitutional Court practically repeated the content of one of its earlier rulings [Constitutional Court ruling no. 19/2004 (V. 26)], which analysed the regulation of the price act (Act LXXXVII of 1990 on the determination of prices) allowing price freezing. The Constitutional Court emphasised repeatedly that certain *direct state interventions regarding prices* might be necessary within the frames of market economy as well. In case of the pharmaceutical market, as drugs are special products, *the state has greater freedom* to intervene into the market processes than in case of other markets, therefore, the violation of the freedom of contract does not arise due to price freezing.

In connection with the price freezing, some petitions referred to violation of *clarity of law* and consequently to the violation of *legal security*. In relation to such petitions the Constitutional Court pointed out that the requirement of the clarity of law does not oblige the legislator to provide a complete and final list of those circumstances the emergence of which would allow the Government to intervene into the economic relations. In line with the altering relations of the market and the great variety of the circumstances giving rise to intervention, the provision of an itemized list is impossible. According to s. 43 of the Act, the Government may apply its competence determined there in case of "averting, eliminating temporary disorder or maintaining the balance of the pharmaceutical market". According to the opinion of the Constitutional Court, "temporary disorder" may be unambiguously determined for the players of the pharmaceutical market, it refers to such an economic reason that makes the intervention of the Government necessary and reasonable. It also limits the sphere of action of the Government that the measure may last only for two years and that its reasonableness shall be supervised at least yearly.

With regard to the above, the Constitutional Court *dismissed* the petitions.

2.3 Rights to supervise promotion activity

S. 20 of the Act regulates the rights of the Health Insurance Supervision, based on which the Health Insurance Supervision has the right to get to know data, confiscate data carriers and search the premises in order to check the keeping of the rules regarding the promotion of drugs and therapeutic equipment.

With regard to the regulation concerning the search of premises, the Constitutional Court found that it *does not violate the right to the integrity of private homes* as the limitation of the right is determined by an act. Allowing the Health Insurance Supervision to search the premises might be a necessary tool for checking the compliance with the rules regarding the promotion of drugs and therapeutic equipment and for detecting bribery, and the limitation is also proportional as it is only possible with prior judicial permission.

According to the Constitutional Court, the violation of the *right to the protection of personal data* cannot be established, as authority control is necessary for the lawful operation of the pharmaceutical

market. Besides, the Act allows data management in a goal orientated way, that is if it is likely that there are such data on the data carrier which are in connection with violation of the rules of drug promotion. As the Constitutional Court did not establish either the violation of the right to the integrity of private homes or that of the right to the protection of personal data, it did not analyse the issue of the violation of human dignity.

With regard to the above, the Constitutional Court *dismissed* those petitions, which aimed at annulling these provisions of the Act.

It is worth mentioning, however, that the standpoint of the constitutional judges was discordant in this regard. According to constitutional judges Dr. Bihari Mihály and Dr. Kukorelli István, the respective regulations of the Act should have been annulled as they provide the Health Insurance Supervision with such power that results in the unnecessary and disproportionate limitation of fundamental rights.

2.4 The non-application of opinion procedure in the course of legislation

With regard that business federations and social organisations were not involved in the preparation of the Act and their opinion was not requested, the Constitutional Court stated that failing to involve such organisations, although violates the provisions of Act XI of 1987 on legislation, does not result in an unconstitutional situation violating the principle of rule of law, therefore it *dismissed* the petitions aiming at determining that the Act is unconstitutional.

2.5 Provisions regarding entry into force

In connection with the provisions of the Act regarding entry into force, the Constitutional Court stated that the preparation time of 30 days determined as a general rule does not violate legal security, and the 45 days entering into force for the payment obligations are in compliance with the preparation time of 45 days determined by the State Budget Act. Therefore, the petitions aiming at determining that the regulations regarding entry into force and/or the entire Act are unconstitutional were *dismissed* by the Constitutional Court.