PRICE WAR IN HUNGARY

1. The first battle: freezing and forced reduction of drug prices

Freezing and 15% forced reduction of prices

The Hungarian Government's decision to freeze and to cut back by 15% drug prices did not come entirely out of the blue, but almost.

In March 2004 the National Health Fund Administration ("NHFA") approached the drug producers (including sales companies of multinational producers) and offered them two rather unpopular alternatives. The producers were offered to sign an agreement with the NHFA providing for a voluntary repayment obligation into the Health Fund of 15% of the producer prices of drugs to which the NHFA paid a contribution (contributed drugs). Those not signing the agreement were supposed to suffer a 15% cutback of the prices of both contributed an non-contributed drugs.

Most of the producers refused to sign the agreement on such a basis.

In return, Health Minister Mr. Kökény decided to take a strong stance and in a new Government Decree (No. 48/2004. (III.19.) ("Freezing Decree") it was provided that those who did not sign the agreement offered by 25 of March 2004 would suffer a 15% cutback and frozen prices for all of their contributed and non-contributed drugs (except for the cheapest product, i.e. under HUF 600) effective as from 1 April 2004.

It is obvious that there were both economic motives (i.e. the ever-growing Health fund spending on medicines) and political logic (the cutback of drug prices is a positive message to voters) behind.

Legal background for drug prices, former Government interventions

To clarify the background, according to the Price Act (Act LXXXVII of 1990), as a general rule the prices for most of the products and services are subject to the agreement of the parties (market prices), whereas certain prices are set by the authorities (official prices).

Under Hungarian Law the drug prices are not considered to be "official prices". As a consequence, under normal circumstances the Government is not entitled to set the drug prices (it may only regulate the trade margins).

Article 19 of the Price Act provides that under exceptional circumstances the Government is entitled to regulate the prices (i.e. set an official price) for any product or service. This is possible *for an interim period of six months but only on the condition that there are changes in taxes or other economic regulators that significantly affect the market or a substantial portion of it*.

In previous years, the practice was that the prices of medicines were formulated after negotiation between the Government and the industry players. Yet, in 2000 and also in 2003 the Government resorted to freezing the prices (but without reduction!); in both cases reference was made to Article 19 of the Price Act.

However, in a price agreement signed in 2003, in which the pharmaceutical producers undertook to make "voluntary" repayment contributions to the Health Fund, the Government promised not to use Article 19 of the Price Act again to freeze prices.

Legal concerns

First of all, those producers who signed the former price agreement in 2003 - in which they undertook to make certain reimbursements to the Health Fund - claimed that the Government breached its promise not to resort to price freezing again. The Government argued that this was a force majeure situation as the unmaintainable shortfall of the Health Fund required an immediate intervention from their side. The producers threatened the Government that they would file a *law suit for damages* based on breach of contractual promises.

One should keep in mind that to actually win such a case against the State would be (to say the least) extremely difficult based on the practice of the Hungarian Supreme Court, as court cases have practically established the immunity of the State for damages caused by legislation. It remains to be seen how this practice will change now that Hungary has entered the EU, where the Member States' liability for damages caused by legislation breaching EU law is an established principle.

Secondly, many industry players argued that the Government/National Health fund abused its dominant position and urged steps from the *Hungarian Competition Office*. The Competition Office was quick to react and took the firm view that it was not within the powers of the Competition Office to judge the lawmaking activity of the State and the Freezing Decree was in fact a piece of legislation.

Thirdly, because Hungary' EU accession was at that time imminent, lawyers had given thought to the potential means of attack under *EU law*. If the Freezing Decree was in breach of directly applicable EU rules, this could be the basis of an action for damages before Hungarian courts by reference to EU laws; a complaint to the Commission could be considered under Article 226 of the EC Treaty or with a reference to unlawful state aid.

In this respect it is worth noting that according to the Freezing Decree and the related subordinated legislation those who signed the agreement with the NHFA received added Health Fund contributions to their contributed drugs and their non-contributed products did not suffer the 15% cutback comparing most of the producers who did not sign the agreement.

Furthermore, industrial players claimed that neither the Freezing Decree nor the Government's previous practices of negotiating agreements on prices was compatible with the EU Transparency Directive (Council Directive 89/105 of 21 December 1988).

To the best of the author's knowledge, no action was so far initiated by industry players based on EU law.

Finally, several petitions were filed with the *Constitutional Court* on the ground that the Freezing Directive and the related subordinated legislation breached the Hungarian Constitution as it was interpreted by the Constitutional Court. Eventually, the Constitutional Court proved to be the most important battleground between the parties.

2. The second battle: the decision of the Constitutional Court

The alleged breaches of the Hungarian Constitution

Of the many arguments that were submitted in the petitions to the Constitutional Court I would like to highlight the following:

Firstly, and most importantly, it was claimed that the conditions based on which it would have been possible for the authorities to set the drug prices (as is explained above, drug prices are normally considered market prices), were not met. The underlying Article 19 of the Price Act could only have been used if *there had been changes in taxes or other economic regulators that significantly affected the market or a substantial portion of it*. However, this was not the case, and therefore the Government did not have the authorisation to issue the Freezing Decree.

Secondly, it was also asserted that the Government intervention was discriminatory without lawful reason, as it differentiated in favour of those producers who signed an agreement with the NHFA and punished those who refused to sign.

Thirdly, it was argued that the price cutback in its effect imposes a taxation type obligation on the producers. In turn, any taxation type obligation can only by contained in an act of Parliament based on the Act on Legislation; a Government Decree or any subordinated legislation is certainly appropriate.

Finally, it was also asserted that Article 19 of the Price Act in itself is contrary to the Constitution as it is too vague, and as such can be the basis of practically any Government intervention in the prices any time: which is against the principle laid down in the Constitution that the Hungarian economy is based on the principles of a market economy.

The decision of the Constitutional Court

In contrast to the previous price freezing cases – where no decisions were made for years – the Constitutional Court acted fairly quickly and rendered a decision substantially in favour of the producers.

The Freezing Decree and the related subordinated legislation were held unconstitutional and were repealed with the effective date of 30 June 2004.

The decision was based on the following main reasons:

(i) the conditions for the exceptional Government intervention in the prices were not met;

(ii) Article 19 of the Price Act does not provide an authorisation for a legislation differentiating between producers;

(iii) the Freezing Decree failed to contain a time limitation for the price freezing and the 15% price cutback, despite the requirement that exceptional Government intervention in prices must be limited in time;

(iv) the Freezing Decree unlawfully punished those producers who did not sign the agreement with the NHFA, even though the producers did not have a legal obligation to sign such an agreement.

Nevertheless, the Constitutional Court did not ensure a long term victory for the pharmaceutical producers as it made clear that Government intervention in drug prices – both for contributed and the non-contributed drugs - is not in itself incompatible with the principles of the Constitution.

Such an intervention can be based on Article 19 of the Price Act or can be done through other means (e.g. through the amendment to the Price Act). However, if the Government wishes to utilise *Article 19 of the Price Act,* it must be done in accordance with the *criteria* established by the Constitutional Court; i.e. *all the conditions must be met; the intervention must be provisional and exceptional, a time limit must be set, repeated intervention is only possible if all the conditions are repeatedly meet*.

3. The third battle: new laws providing powers for the Government to freeze drug prices

In the critical situation after the Constitutional Court decision, the Government quickly pushed through an *amendment to the Price Act*. The amendment (Article 19/A) provided new powers for the Government to freeze drug prices (but not to reduce prices!) *for a period of 9 months in the event that such an action is necessary to eliminate or avert disorder on the drug market or to maintain the balance of such market*. According to the new law, an exception may be requested from the Health Minister under very limited circumstances.

The amendment was in force from 26 June 2004, just in time to maintain the effect of the 15% cutback and the price freezing made by the Freezing Decree - which was repealed by the Constitutional Court with an effective date of 30 June 2004!

4. Peace talks: the new price agreement with the Government

Although Article 19/A of the Price Act was in place, it was not yet tested by the Constitutional Court, nor were the EU law arguments and the possible damages claim. In these circumstances both the State and the producers thought that there were good reasons to be moderate and they rushed to find compromises embodied in a new price agreement.

The agreement was signed before 30 June 2004, so the new weapon, Article 19/A of the Price Act, was in fact not used by the Government.

The new price agreement between the Government and the producers was based on the following pillars:

(i) in 2004 non-contributed drugs will remain at the price level established by the Freezing Decree, i.e. with the 15% price reduction; thereafter the producers will be free to establish the prices of non-contributed drugs;

(ii) until the end of 2006 prices of contributed drugs will also remain at the level established by Freezing Decree (with the 15% price reduction); increase of prices is only possible as from 2005 and on the condition that there is a change in the HUF/EURO exchange rate, greater than +/- 6,25%;

(iii) the Government will cover a part of the producers' losses deriving from maintenance of the 15% price cutback;

(iv) the Government undertakes to increase its medicine relating spending by 5-5%, both in 2005 and 2006;

(v) the Government will refrain from exceptional price intervention based on either Article 19 or Article 19/A of the Price Act.

It remains to be seen whether by virtue of the new agreement the desired long term stability of prices and Health Fund spending will be achieved, but it can be seen from the above that serious compromises were made from both side to reach a consensus.