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Contribution on the Pharmaceutical Industry

2015 State Budget Law Proposal presented to the Portuguese Parliament on October 15, 2014 includes a provision authorizing the Government to legislate on the creation of a contribution on the pharmaceutical industry ("CPI") and its regime.

The main features of the CPI regime deriving from the Proposal, and listed below, give rise, among others, to serious doubts as to its compatibility with the general principles, including constitutional principles, that govern the Portuguese tax system, in particular and immediately by overburdening a group of companies operating in the pharmaceutical sector.

Therefore, the CPI regime will certainly be subject to a close scrutiny by its taxable persons and, if approved as proposed, it will give rise to tax ligation. Nevertheless, we will actively monitor the evolution of the discussion of this Proposal in the Parliament.

Purpose

The CPI aims at the sustainability of the National Health System ("NHS"), concerning medicinal products expenditure.

Taxable persons

The CPI will be due by entities that undertake the first sale for consideration in the national territory of medicinal products for human use, whether holders of a marketing authorization or registration, their representatives, intermediaries, wholesale distributors or mere suppliers of medicinal products under exceptional under an exceptional use authorization, or an exceptional authorization.

Taxable basis

The CPI will be levied on the total amount of the monthly sales of medicines for:

> Medicinal products which price is reimbursed by the State;

> Medicinal products subject to a restricted medical prescription;

> Medicinal products that have an exceptional use authorization or an exceptional authorization;

> Medicinal gases, blood and human plasma products;

> Other medicinal products intended for hospital; and

> Orphan medicinal products.

The total amount of sales to be considered regarding **medicinal products which price is reimbursed by the State** is that corresponding to the part of the retail selling price, net of VAT and the fee on the sale of medicines ("FSM").

In all other cases, the total amount of sales to consider will be based on the lowest price, deducted from VAT and the FSM, of the following:

> The retail selling price, if applicable;

> The maximum price considered appropriate to the medicine, if applicable;

> The lowest selling price, net of discounts or other commercial conditions, actually charged, by the taxable person or by another person, on the sales to the Shared Services of the Health Ministry ("SSHM" – *Serviços Partilhados do Ministério da Saúde - SPMS*), regional health administrations, hospitals and other institutions of the NHS, in the preceding 12 months.

Rates

CPI rates will vary between:

> 0.5% and 5% for:

a) Medicinal products which price is reimbursed by the State, included in homogeneous clusters;

b) Medicinal products which price is reimbursed by the State, not included in homogeneous clusters with a~~n~~ marketing authorization granted for 15 years or more, with a price below 10 euros.

c) Medicinal gases, blood and human plasma products.

d) Orphan medicinal products;

> 7% and 12% for medicinal products which price is reimbursed by the State, not covered under the previous cases.

> 10% and 15% for medicinal products subject to a restricted medical prescription, medicinal products that have an exceptional use authorization or an exceptional authorization and other medicinal products intended for use in hospitals.

The Proposal provides as well for the establishment of transitional rate arrangements to be applicable until the CPI final rates are specifically defined.

Assessment and payment

Although the 2015 State Budget Law Proposal does not provide for assessment and payment rules, the Government will be authorized to establish them.

Notwithstanding the above, it is proposed that the Tax Authorities will retain 3% of the CPI proceeds, which shall constitute own revenues, as compensation for expenses incurred with CPI's assessment and payment.

Non-deductibility

Under the proposed regime of the contribution on the pharmaceutical industry, the CPI is not eligible as a deductible cost for Corporate Income Tax ("CIT") purposes at the level of the relevant taxable person.

Tax Infringements

The infringement of tax obligations established under the CPI regime will be subject to General Tax Infringements Regime (“GTIR”) rules.

Revenue assignment

According to the proposed CPI regime, CPI revenue will be assigned to the NHS, run by the Central Administration of the Health System, IP (“CAHS” – *Administração Central do Sistema de Saúde, I.P. – “ACSS”*) and will constitute NHS’ own revenue.

Final note

On a final note, we highlight that the first allusion to the CPI emerges from the Fiscal Strategy Document (“FSD”). In this Document, reference is made to the agreement, which had been reached for previous years and was at that time under negotiation for the years of 2014 and 2015, between the Health Ministry and the pharmaceutical industry, aimed at setting limits for public expenditure on medicinal products, in order to achieve the objectives – that had been set in the Memorandum of Understanding on Specific Economic Policy Conditionality, signed in 2011 – to reduce public expenditure on medicinal products to 1% of GDP.

The FSD makes a clear reference to the priority granted to reaching an agreement with the pharmaceutical industry, identifying, however, the possibility of creation of a contribution on the pharmaceutical industry ("applying a «Tax Clawback»") only in the event the aforementioned agreement could not be reached.

In this context, the proposed establishment of the CPI seems to depart from the FSD forecast, to the extent that, in 2014 – as in the preceding years, we may restate – the agreement to reduce public expenditure on medicinal products was concluded between the Government and the pharmaceutical industry.

Comparing the financial contributions made by pharmaceutical companies under the above mentioned agreement with the CPI regime raises certain issues which may deserve further analysis. For illustrative purposes, the fact that CPI is not eligible as a cost for CIT purposes, in itself highly debatable, proves to be particularly hurting if account is taken of the fact that eligibility as a deductible cost for CIT purposes is expressly provided for financial contributions made under the agreement signed with the Government.

It may thus be anticipated that this contribution on the pharmaceutical industry will trigger a strong reaction from the companies that will be CPI’s taxable persons, challenging its legality or even its conformity with the Portuguese Republic Constitution.

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