



NEWSLETTER | HEALTH LAW

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I. AMENDMENTS TO THE FRAMEWORK OF THE PHARMACEUTICAL INDUSTRY'S ACTIVITIES IN THE 2015 STATE BUDGET

The 2015 State Budget, enacted by Law No 82-B/2014, published on 31 December ("2015 SB"), has established the following rules concerning the Pharmaceutical Industry, which may have a significant impact on the revenues and charges attributable to holders of marketing authorisation ("MA") for medicinal products:

- 1) Article 166, amending the scope of the fee applicable to the sale of medicinal products** established in Decree-Law No 282/95 of 26 October. With this amendment, the scope of application of the fee on the sale of medicinal products is now the same as the one of the extraordinary contribution from the pharmaceutical industry, that is, this fee will now apply to "entities selling for the first time, for valuable consideration, in the national territory, medicinal products for human use, irrespective of whether they are holders of a marketing authorisation or registration, or their representatives, intermediaries, wholesalers or simply suppliers of medicinal products under an exceptional use authorisation, or an exceptional authorisation, for medicinal products";
- 2) Article 167, amending the pricing system for medicinal products** for hospital use, with a view of reducing the prices of medicinal products acquired by the national health system hospitals, introducing provisions that lay down new maximum limits for the price of sale to the warehousemen of all prescription only medicinal products whenever the same are purchased by health national system hospitals. This amendment also lays down a new, stricter sanction mechanism, which even provides for the strict liability of the holders of marketing authorisations, with regard to the obligations relating to medicinal products pricing;
- 3) Article 168, establishing an extraordinary contribution for the pharmaceutical industry ("PI Contribution"),** as follows:
 - o Reimbursed medicinal products (including in related groups) 2.5%;
 - o Not included in related groups and with a marketing authorisation granted 15 or more years ago, 2.5% and with a price of less than 10 euro, other cases 10.4%);
 - o Restricted prescription only medicinal products, as well as those in respect of which an exceptional use authorisation has been issued or that are intended for hospital use (14.3%), medicinal gases and products derived from human blood and human plasma (2.5%), orphan drugs (2.5%).

To begin with, it should be noted that there is an alternative scheme to the PI Contribution. Pursuant to the law, the entities that may come to join the agreement between the Ministries of Finance and of Health and the Pharmaceutical Industry, represented by APIFARMA, on 21 November 2014 ("Agreement") are exempted from the PI Contribution. Considering this alternative, below is a brief analysis of the PI Contribution as opposed to the scheme set out in the Agreement.

PI CONTRIBUTION

The PI Contribution raises a number of questions with regard to its lawfulness and constitutionality.

As a first remark, the 2015 SB qualifies the PI Contribution as “extraordinary contribution”, which could indicate its qualification as special contribution. But real special contributions are subject to the principle of equivalence, and are only valid if they arise as a result of (i) a consideration for a public activity or (ii) their function of socialization of negative or positive externalities.

However, the PI Contribution does not meet either requirement, which raises the question of the breach of the principle of equivalence. Accordingly, the above-mentioned extraordinary contribution, should it be defined as special contribution, would be unconstitutional, on account of the breach of the principle of tax equality enshrined in Article 13 of the Constitution, and of which the principle of equivalence is mere an expression.

However, it should be noted that the 2015 SB does not expressly announce the PI Contribution as temporary, which precludes it from being defined as a special contribution and, therefore, of being underpinned by the principle of equivalence. Indeed, instead of a special contribution, the PI Contribution is closer to a hidden tax, and would seem to be aimed at unilaterally and coactively collecting revenue.

Accordingly, even qualifying the PI Contribution as **special tax or tax with extra-fiscal purposes**, and making the same subject to the legal framework of taxes, the same would, even then, in our opinion, be unconstitutional. To begin with, on account of the breach of the principle of fiscal capacity, as the contribution in question individualises an arbitrary group of taxable persons, in respect of which there are no signs of any increased economic strength to justify the additional tax.

Secondly, because it breaches the single nature of income tax, since it is configured as a taxation of assets which cannot be deducted from income tax and cannot be qualified as wealth tax either.

Thirdly, because the PI Contribution taxes income without considering specific deductions and the actual situation of companies, and therefore does not uphold the principle of fiscal capacity of legal persons, which points toward a taxation of companies in accordance with their actual income, which also causes its unconstitutionality.

Moreover, as referred to above, the scope of application of the PI Contribution is the same as that of the fee on the sale of medicinal products, that is, the entities subject to the PI Contribution are also those “selling for the first time, for valuable consideration, in the national territory, medicinal products for human use, irrespective of whether they are holders of a marketing authorisation or registration, or their representatives, intermediaries, wholesalers or simply suppliers of medicinal products under an exceptional use authorisation, or of an exceptional authorisation, for medicinal products”; although double taxation is not in and of itself prohibited, in this case, the accumulation of the PI Contribution with a fee

charged on the same taxable matter strengthens the argument of the breach of the principle of proportionality and of fiscal capacity.

It is therefore concluded that it is possible to sustain the unconstitutionality of the PI Contribution, irrespective of the same being set as a special tax, a tax with extra-fiscal purposes or a special contribution.

AGREEMENT

As referred to above, the entities concerned by the PI Contribution may choose to join the Agreement entered into between the Ministries of Finance and of Health and the Pharmaceutical Industry, represented by APIFARMA, whereby they will be exempted from the payment of the PI Contribution.

This Agreement establishes the value of the contribution of the Pharmaceutical Industry towards expenses with medicinal products in the scope of the national health services, aiming to reduce public expenditure with medicinal products. In this connection, the Agreement established the payment of a contribution by the companies associated with APIFARMA of a minimum value of EUR 135,000,000 (having as reference the total value of EUR 180,000,000 for the entire pharmaceutical industry); the sum to be paid by each company associated with APIFARMA must be determined in accordance with a formula to be established by APIFARMA.

The determination of the above-mentioned contribution by the Pharmaceutical Industry with a view to reducing public expenditure with medicinal products in 2015, is underpinned by an objective of public expenditure with medicinal products of the national health system of EUR 2,000,000,000. Taking this objective into account, the Agreement also provides for an **additional contribution by the companies that joined the Agreement**, to the effect of **these companies paying the amount of public expenditure with medicinal products sustained by the national health system, in excess of such maximum objective of EUR 2,000,000,000.**

Indeed, pursuant to Clause 3(7) of the Agreement, the payment of the amount in excess of such maximum expenditure objective, must be made by the companies that joined the Agreement during the first quarter of 2016. Additionally, the same provision sets out that "The companies associated with APIFARMA and that joined the Agreement are only responsible for the part attributable to them in the increase of the public expenditure with medicinal products in the national health service, in the proportion of the corresponding market share."

It should also be mentioned that the content of the Agreement is very similar to the one entered into by the parties, with the same purpose, for 2014. And the latter also established, in Clause 3(7) thereof an increase of the contributions from each company associated with APIFARMA that joined the Agreement, in case the 2 thousand million euro expenditure limit is exceeded.

II. NATIONAL LEGISLATION

Ordinance No 222/2014 - *Diário da República* (Portuguese official gazette) No 213/2014, Series I of 2014-11-04

Ministry of Economy and Health

Setting out the pricing and contribution scheme to which the reagents (test strips) for the determination of blood glucose, ketone and ketonuria and needles, syringes and lancets intended for persons with diabetes are subject.

Decree No 13363/2014 - *Diário da República* (Portuguese official gazette) No 213/2014, Series II of 2014-11-04

Ministry of Justice and of Health – Offices of the Minister of Justice and of the Minister of Health

Determining the setting up of the commission for the monitoring of the execution of the legal framework of the compulsory in-patient care.

Ordinance No 227/2014 - *Diário da República* (Portuguese official gazette) No 215/2014, Series I of 2014-11-06

Ministry of Health

Defining the specific central buying activity for the health area that is the task of the SPMS, E. P. E. - Serviços Partilhados do Ministério da Saúde, E. P. E.

Decree No 13500/2014 - *Diário da República* (Portuguese official gazette) No 216/2014, Series II of 2014-11-07

Ministries of Finance, of Internal Administration and of Health – Offices of the Assistant Secretary of State and of Budget, of the Assistant Secretary of State to the Minister of Internal Administration and of the Assistant Secretary of State to the Minister of Health

Establishing that the reimbursement to pharmacies by the health care system of *Guarda Nacional Republicana* and of *Polícia de Segurança Pública* is assumed by the National Health Service.

Decree No 13522/2014 - *Diário da República* (Portuguese official gazette) No 216/2014, Series II of 2014-11-07

Ministry of Health – Directorate General for Health

Appointing the members of *Comissão Nacional da Saúde Materna, da Criança e do Adolescente* (National Committee for the Maternal, Child and Youth Health).

Decree No 13523/2014 - *Diário da República* (Portuguese official gazette) No 216/2014, Series II of 2014-11-07

Ministry of Health - INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I. P.

Sub-delegation of powers of the vice-president of the Advisory Board of INFARMED, I. P., relating to the Quality Verification Board.

Decree No 13836-A/2014 - *Diário da República* (Portuguese official gazette) No 220/2014, 1st Supplement, Series II of 2014-11-13

Ministry of Health – Office of the Secretary of State of Health

Declaring the outbreak caused by the legionella bacteria a serious health emergency and identifying the hospitals where the adoption of measures of exception is required.

Decree-Law No 173/2014 – *Diário da República* (Portuguese official gazette) No 224/2014, Series I of 2014-11-19

Ministry of Health

Amending for the third time Decree-Law No 124/2011, of 29 December, which enacted the Organic Law of the Ministry of Health, amending for the first time Decree-Law No 35/2012, of 15 February, which enacted the organic structure of Administração Central do Sistema de Saúde, I.P., and amending for the second time Decree-Law No 22/2012, of 30 January, which enacted the organic structure of Administrações Regionais de Saúde, I.P.

Regulation N° 529/2014 - *Diário da República* (Portuguese official gazette) No 228/2014, Series II of 2014-11-25

Veterinary Association

General Regulation for Specialties of the Veterinary Association.

Portaria No 250/2014 - *Diário da República* (Portuguese official gazette) No 231/2014, Series I of 2014-11-28

Ministries of Finance and Health

Regulating the handling of the tender procedure for the recruitment for public service posts, in the scope of the special nursing career.

Decree No 15013/2014 - *Diário da República* (Portuguese official gazette) No 239/2014, Series II of 2014-12-11

Ministries of Finance and Health – Offices of the Secretary of State of Treasury and of the Secretary of State of Health

Capital increase of *EPE* hospitals, in kind (conversion of debt in to capital).

Decree No 15568/2014 - *Diário da República* (Portuguese official gazette) No 248/2014, Series II of 2014-12-24

Ministry of Health – Office of the Secretary of State of Health

Determining that the IT platform, designated "Portal do PEBC e Ecop.AP do Ministério da Saúde", will mandatorily be used in all public entities of the health sector that form part of the PEBC e Eco.AP.

Resolution (excerpt) No 2374/2014 - *Diário da República* (Portuguese official gazette) No 248/2014, Série II de 2014-12-24

Centro Hospitalar de Vila Nova de Gaia/Espinho, E. P. E.

Transition to the 40 hours scheme.

Resolution (excerpt) No 2375/2014 - *Diário da República* (Portuguese official gazette) No 248/2014, Series II of 2014-12-24

Centro Hospitalar de Vila Nova de Gaia/Espinho, E. P. E.

Transition to the 40 hours scheme.

Decree-Law No 188/2014 - *Diário da República* (Portuguese official gazette) No 251/2014, Series II of 2014-12-30

Ministry of Finance

Extinguishing *Fundo de Apoio ao Sistema de Pagamentos do Serviço Nacional de Saúde*, created by Decree-Law No 185/2006, of 12 September.

Decree No 15714/2014 - *Diário da República* (Portuguese official gazette) No 251/2014, Series II of 2014-12-30

Ministry of Health – Office of the Secretary of State of Health

Laying down provisions in connection with *Serviços Partilhados do Ministério da Saúde*, E. P. E. (SPMS, E. P. E.), relating to Public Procurement Contracts setting out the conditions of supply of incontinent material and pressure relief devices.

Decree (excerpt) No 15715/2014 - *Diário da República* (Portuguese official gazette) No 251/2014, Series II of 2014-12-30

Ministry of Health – Office of the Secretary of State of Health

Laying down provisions in connection with *Serviços Partilhados do Ministério da Saúde*, E. P. E. (SPMS, E. P. E.), relating to Public Procurement Contracts setting out the conditions of supply of Group 4 Medicinal products: Blood.

Law No 82-B/2014 - *Diário da República* (Portuguese official gazette) No 252/2014, 1st Supplement, Series I of 2014-12-31

Parliament

2015 State Budget.

III. EU LEGISLATION

Commission Delegated Regulation (EU) No 1252/2014 of 28 May 2014 supplementing Directive 2001/83/EC of the European Parliament and of the Council, with regard to principles and guidelines of good manufacturing practice for active substances for medicinal products for human use.

IV. INFARMED

Information Circular No 251/CD/8.1.6 Date: 16/12/2014

Ebola experimental treatments still in an early stage of development.

CONTACT

CUATRECASAS, GONÇALVES PEREIRA & ASSOCIADOS, RL

Sociedade de Advogados de Responsabilidade Limitada

LISBOA

Praça Marquês de Pombal, 2 (e 1-8º) | 1250-160 Lisboa | Portugal

Tel. (351) 21 355 3800 | Fax (351) 21 353 2362

cuatrecasas@cuatrecasas.com | www.cuatrecasas.com

PORTO

Avenida da Boavista, 3265 – 5.1 | 4100-137 Porto | Portugal

Tel. (351) 22 616 6920 | Fax (351) 22 616 6949

cuatrecasasporto@cuatrecasas.com | www.cuatrecasas.com

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