First Update of the Memorandum of Understanding on Specific Economic Policy Conditionality - Health Care System

During the following weeks, the representatives of the Troika will be in Portugal to monitor the progress on the implementation of the measures established in the Memorandum of Understanding between Portugal and the EU – ECB – IMF, which has an updated version since 1st September 2011:

The objectives initially drawn for the health sector were kept in the new version of the Memorandum, namely the improvement of efficiency and effectiveness in the health care system, inducing a more rational use of services and control of expenditures and generating additional savings in the area of pharmaceuticals to reduce the public spending on pharmaceuticals to 1.25 per cent of GDP by end 2012 and to about 1 per cent of GDP in 2013 (in line with EU average). In addition to the creation of additional savings in hospital operating costs, a new strategy to eliminate arrears is devised.

In terms of Financing, one of the intended measures was to cut substantially (by two thirds overall) tax allowances for healthcare, including private insurance, which had to be complied with by the end of October of 2011.

When it comes to pricing and reimbursement of pharmaceuticals, the Memorandum of May indicated that the maximum price of the first generic introduced in the market, should be set to 60% of the branded product with same active substance, and in the new version updates this amount to 50% (This measure has been included in a legal framework approved by the Portuguese Government).

The updated version of the Memorandum also foresees a new measure which will transfer the responsibility of pricing medicines from the Ministry of Economy to the Ministry of Health, namely to the INFARMED (which integrates this Ministry). The revision of the existing reference-pricing system based on international prices by changing the countries of reference to the three EU countries with the lowest price levels or countries with comparable GDP per capita levels is still provided in the Memorandum (This measure has also been included in a Governmental legislative act).

The measures concerning the prescription and the monitoring of prescription for medicinal products has no alterations, namely making the electronic prescription for medicinal products and diagnostic covered by public reimbursement fully compulsory for physicians in both the public and private sector (Q3 2011) and also the improvement of the monitoring system of prescription of medicines and diagnostic (This measure has been partially included in a legal framework approved by the Government).

The physicians continue to be induced, at all levels of the system, both public and private, to prescribe generic medicines and the less costly available branded product (Q3 2011), simultaneously with the removal of all effective entry barriers for generic medicines (Q4 2011) and also the establishment of clear rules for the prescription of drugs and the realisation of complementary diagnostic exams (Q4 2011).

In the Pharmacies sector, the implementation of the existing legislation regulating pharmacies, and the change of the calculation of profit margin regressive mark-up and a flat fee for wholesale companies and pharmacies, for the purpose of reducing of public spending on pharmaceuticals, remains the main relevant measures (these measures have, as well, been included in a legal framework approved by the Government).

The set up of a legislative and administrative framework for a centralised procurement system for the purchase of medical goods in the NHS, through the SPMS, to reduce costs (Q3 2011), continues as an effective measure, and there are also measures to increase competition among private providers and reduce by at least 10 per cent the overall spending (including fees) of the NHS with private providers delivering diagnostic and therapeutical services to the NHS by end 2011 and by an additional 10% by end 2012 (Q4 2011).

Lastly, regarding the hospital services, there were new updates brought by the Memorandum. Besides a binding timetable to clear all arrears in the health sector, as well as, the introduction of standardised and tight control procedures for all health sector entities, a new mechanism will be put into place to ensure strong coordination between the Ministry of Health and the Ministry of Finance for the application of the same monitoring and control criteria to all types of hospitals (Q3 2011).

There is also a new measure which will change the existing accounting framework and adopt accounting standards in line with the requirements for private companies and other State Owned Companies, therefore improving the management of the enterprises and the quality of the financial oversight by the general government (Q3 2011).

One of the objectives already defined in the prior version of the Memorandum was the reorganisation and rationalisation of the hospital network through specialisation and concentration of hospital and emergency services and joint management (building on the Decree-Law 30/2011) joint operation of hospitals, therefore allowing additional cuts in operating costs by at least 5 per cent in 2013. The Memorandum now adds that from 2011 to 2013, hospital operational costs must be reduced by at least 15% compared to 2010 level (Q2 2012).

The annual update of the inventory of all practising doctors by specialty, age, region, health centre and hospital, public and private sector, should have been implemented in the end of October 2011. The inventory will subsequently be extended to other categories of staff. It will also include figures for the autonomous regions of Madeira and Azores (Q1 2012).

The introduction of rules to increase mobility of healthcare staff (including doctors) within and across health regions, includes the adoption for all staff (including doctors) flexible time arrangements, with a view of reducing by at least 20% spending on overtime compensation in 2012 and another 20% in 2013, instead of the 10% initially defined in the Memorandum of May.

This updated version of the Memorandum, within the Regional Health Authorities, provides for the improvement of monitoring, internal control and fiscal risks management systems of the Regional Health Authorities by Q4 2012.

I. LEGISLATIVE PROPOSALS

Required Arbitration for Disputes between Generic and Reference Medicinal Products

Legislative Proposal No 13/XII, of 1 September, 2011 – Establishes an alternative mechanism of dispute settlement that issues, in a faster way, a decision related to the violation of intellectual property rights, resorting to arbitration. The arbitration will be compulsory when a generic medicinal products company requires a marketing authorization to INFARMED, or a price approval or a reimbursement of the medicine from the State. The legislative proposal establishes the reduction of the price of generic medications in 50% of the selling price of the reference medicinal product.

Prices of Reimbursed Medicinal Products subjected to Medical Prescription

Legislative Proposal of 28 September, 2011 – Reviews the pharmaceuticals policy in Portugal, namely through the adoption of a new methodology of selling prices of reimbursed medicinal products subject to medical prescription. This legislative initiative aims to guarantee a reduction in the public spending with medicinal products and create incentives on the selling of less costly pharmaceutical products, complying with rules laid down in the Memorandum of Understanding. The reference countries will now be Spain, Italy and Slovenia.

Nationwide Registration of Health Data

Legislative Proposal No 23/XII of 29 September, 2011 – Defines the conditions of treatment of personal data which are health related, creating a nationwide data registration system and resorting to information technologies, within the National Health Service.

Electronic Prescription by INN

Legislative Proposal No 92/2011 of 10 October, 2011 – The prescription of medicinal products by International Nonproprietary Name becomes compulsory, for the purpose of promoting the prescription and consumption of generics.

I. NATIONAL LEGISLATION

Support Fund to the Payment System of the National Health Service

Dispatch 10788/2011, published in the Official Gazette, 2 Series, number 168, of 1 September 2011 – Nomination of members of the Commission of the Support Fund to the Payment System of the National Health Care Service.

Inclusion of new pharmaceuticals in the special regime of reimbursement of medicinal products

Ministerial Order No 267-A/2011, dated 15 September, 2011, published in the Official Gazette, 1 Series, number 125, of 15 September, 2011 – Defines the conditions of inclusion of new medicinal products in the respective regime of reimbursement, both medicinal products used for treatment of specific pathologies and medicinal products used by special groups of patients covered by the NHS.

II. LEGISLATION OF THE EUROPEAN UNION

Legislative Proposals Adopted by the Commission in the Public Health Domain

Regulation Proposal COM (2011) 353, of the Council and the European Parliament, dated 22 June of 2011, published in the Official Journal of the European Union, of 8 September, 2011 – Proposal on food intended for infants and young children and on food for special medical purposes.

Directive Proposal COM (2011) 385, of the Council, dated 27 June of 2011, published in the Official Journal of the European Union, of 8 September, 2011 – Establishes requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption.

Directive Proposal COM (2011) 348, of the Council and the European Parliament, dated 27 June of 2011, published in the Official Journal of the European Union, of 8 September 2011 - On the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields) (XXth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC).

Financial Aid of the Union to the Laboratories of Reference of the EU

Commission Implementing Regulation (EU) No 926/2011 of 12 September 2011, published in the Official Journal of the European Union of 17 September, 2011 – The Regulation refers to the financial aid of the Union to the reference laboratories of the EU, for animal food and the animal health sector and establishes the implementing rules of the Regulation No 882/2004 and the Decision No 2009/470/CE, in the part concerning the rules for granting financial support of the Union. The Regulation is applicable to all the reference laboratories of the EU whose framework partnership agreements come to an end in 2011 and for EU reference laboratories whose framework partnership agreements are terminated by mutual agreement.

European Union Decisions on Marketing Authorizations in respect of Medicinal Products from 1 July 2011 to 31 August 2011

Informations 2011/C 316/01 and 2011/C 316/02, published in the Official Journal of the European Union of 26 October of 2011 - Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 July 2011 and 31 August 2011 (published pursuant to Article 13 (medicinal products for human use) or Article 38 (veterinary products) of Regulation (EC) No 726/2004 of the European Parliament and of the Council, taken pursuant to Article 34 of Directive 2001/83/EC or Article 38 of Directive 2001/82/EC.)

Adaptation of Certain Substances of Cosmetics to Technical Progress

Directive No 2011/84/UE, of the Council, dated 20 September of 2011, published in the Official Journal of the European Union, of 29 October 2011 – Amends the Directive 2011/84/UE, concerning cosmetic products, to adapt its Annex III to technical progress. Many relevant amendments are introduced regarding the restrictions and conditions of the use of hydrogen peroxide, which are laid down in the first part of Annex III of the Directive 76/768/CEE. The Scientific Committee on Consumer Products confirmed that a maximum concentration of 0.1% of hydrogen peroxide present in oral products or released from other compounds or mixtures in those products is safe. It should therefore be possible to continue to use hydrogen peroxide in that concentration in oral products, including tooth whitening or bleaching products.

III. INFARMED – NEWS

Medical Devices for Diagnostic in vitro – Rapid Detection of HIV

Publication of a List of medical devices for diagnostic in vitro – After several requests for information, from several Health entities and organizations, INFARMED prepared a list of medical devices for in vitro diagnostic, specifically for the detection, confirmation and quantification, in human samples, of infection indicators of HIV (HIV 1 and 2) – Rapid Tests, to be updated quarterly. All the devices registered by Portuguese distributors in the on-line register system of INFARMED until the end of September 2011 were considered in the elaboration of this list, and only the test currently marketed in Portugal were included.

Request of Medicinal Products Samples given to the NHS Hospitals for Free

Information Note N.º 180/CD, of 16 September, 2011 – The INFARMED reminds that the medicinal products samples are not meant for patient treatment and should not be accepted by the NHS Hospitals for this purpose. However, in a situation where the NHS Hospitals lack medicinal products that are not marketed or are still under prior evaluation, for indispensable and justifiable treatment of certain patients, can always require samples that allow them to obtain the medicinal products to treat the patients adequately.

Content of the Information Contained in the Medical Devices Manufacturer's Address

Information Note 181/CD, 21 September 2011 – For the purpose of supervision of the medical devices market, the *Central Management Committee* (CMC), on 7th of June of 2011, issued a Decision on the content of the Information that should be contained in the address of the medical devices manufacturer and his legal representative, when applicable, that should be contained in the labelling and also in the instructions manual. The address of the legal residence or headquarters shall allow a post contact with the producer and should include elements such as Street/Avenue, Number/Floor, Zip Code, Town/Council/District and Country.

Expiry of Reimbursements (September 2011)

Resolution of the Board of INFARMED of 22 September, 2011 – Publishes the final List of medicinal products for which it was decided the expiry of the reimbursement, regarding the lack of trade during the period of September 2011.

Electronic Transmission Procedures with INFARMED

Information Note of 30 September, 2011 – The electronic transmission tests procedure of Individual *Case Safety Reports,* to be adopted by owners of marketing authorizations/ Clinical Trial Promoters, as well as the supporting documentation are available in INFARMED's *website*.

Extension of the Regulation on the Amendments to the terms of Marketing Authorizations to the National Procedure

Information Note Nº200/CD of 3 October, 2011 – In the context of the European Commission's initiative in relation to the improvement of the legislation related to the amendments of the terms of Marketing Authorizations, a revision to the Regulation No 1234/2008 of the Commission is to be made, extending its scope to the national procedure, therefore including Portugal.

- **Judicial Decision - Sildenafil Siltop and Sildenafil Farmoz**

Information Note No 204/CD of 13 October, 2011 – The INFARMED disclosed that the companies Tecnimede - Sociedade Técnico-Medicinal, S.A. and Farmoz - Sociedade Técnico Medicinal, S.A., are forbidden to produce, offer, store, introduce in the Portuguese market, use, import or possess the generic medicinal products Sildenafil Siltop and Sildenafil Farmoz, which are also seized.

- **Expiry of Reimbursements (October 2011)**

Resolution of the Board of INFARMED of 20 October, 2011 – Publishes the final List of medicinal products for which it was decided the expiry of the reimbursement, regarding the lack of trade during the period of October 2011.

IV. ACSS – NHS Centralised Purchases Authority

- **Medical Services**

Regulation No 23, 14 September, 2011 – Hiring of Medical Services in the modality of provision of services – Dispatch No 10428/2011, 18th of August.

- **Access to the NHS**

Regulation No 24 of 15 September, 2011 - Concerns the access to the National Health Service by national citizens resident abroad.

- **Program for Health Professionals**

Information Note No 30, of 28 September, 2011 – The XXXI Program of Exchange for Health Professionals - HOPE 2012 'Aging of Patients and Health Professionals: Challenges for the Hospitals and Health Services'.

VI. COMUNICATIONS – European Documents

- **Concentration Lenovo/Medion**

Communication 2011/C 258/02, of the European Commission, published in the Official Journal of the European Union of 2 September 2011 - Non-opposition to a notified concentration (Case COMP/M.6196 — Lenovo/Medion).

- **Concentration Teva/Cephalon**

Communication 2011/C 261/07, of the European Commission, published in the Official Journal of the European Union of 3 September 2011 - Prior Notification of a Concentration (Case COMP/M.6258 — Teva/Cephalon).

- **Concentration Procted & Gamble/Teva OTC business**

Communication 2011/C 264/14, of the European Commission, published in the Official Journal of the European Union of 8 September 2011 – Prior Notification of a Concentration (Case COMP/M.6280 — Procter & Gamble/Teva OTC business).

- **Concentration Galenica/Fresenius Medical Care/Vifor Fresenius Medical Care Renal Pharma JV**

Communication 2011/C 264/12, of the European Commission, published in the Official Journal of the European Union of 8 of September 2011 - Prior Notification of a Concentration (Case COMP/M.6091 — Galenica/Fresenius Medical Care/Vifor Fresenius Medical Care Renal Pharma JV).

- **Concentration Apax/Kinetic**

Communication 2011/C 270/07, of the European Commission, published in the Official Journal of the European Union of 13 September 2011 - Prior Notification of a Concentration (Case COMP/M.6343 — Apax/Kinetic Concepts).

- **Concentration Arla Foods/ Allgäuland**

Communication 2011/C 270/07, of the European Commission, published in the Official Journal of the European Union of 13 September 2011 - Prior Notification of a Concentration (Case COMP/M.6348 — Arla Foods/Allgäuland).

- **Concentration Dow/Mitsui/Brazilian Polyethylene**

Communication 2011/C 292/04, of the European Commission, published in the Official Journal of the European Union of 5 October 2011 - Prior Notification of a Concentration (Case COMP/M.6391 — Dow/Mitsui/Brazilian Polyethylene JV) — Candidate case for simplified procedure.

- **Concentration J&J/Synthes**

Communication 2011/C 295/08, of the European Commission, published in the Official Journal of the European Union of 7 October 2011 - Prior Notification of a Concentration (Case COMP/M.6266 — J&J/Synthes).

- **Concentration Solvay/Rodhia**

Communication 2011/C 295/08, of the European Commission, published in the Official Journal of the European Union of 13 October 2011 - Non-opposition to a notified concentration (Case COMP/M.6230 — Solvay/Rhodia).

- **Marketing Authorizations List**

Information from the Permanent Committee of EEA/EFTA States, published in the Official Journal of the European Union of 13 October 2011 - List of marketing authorizations granted by the EEA EFTA States for the second half of 2010, regarding medicinal products.

- **Resistance to Antimicrobial Drugs**

Recommendation of the European Commission, date 27 October of 2011, published in the Official Journal of the European Union of 28 October 2011 - Commission initiative of on the research Joint Programming Initiative 'The Microbial Challenge — An Emerging Threat to Human Health'.

- **Harmonization of Consumer Claims in Cosmetic Products**

Opinion of the European Economic and Social Committee, dated 13 July 2011, published in the Official Journal of the EU of 29 October 2011 – Opinion on 'Harmonisation of consumer claims in cosmetic products' (own-initiative opinion) for the benefit of companies operating in the internal market, for consumers and for control bodies.

VII. NATIONAL CASE-LAW

Administrative Central Court (South) – Registry of a Community Marketing Authorization of a Medicinal Product

Case No 08045/11 of 20 October 2011

Summary:

I.The registry acts issued by INFARMED, of marketing authorizations granted in a centralized procedure by a community entity, for example, generic medicinal products, has the nature of an administrative act – Article 54(2) of the Decree-law 176/06 of 30 August and the Deliberation No 147/CD/2008 of INFARMED's Board.

II. The marketing authorization, which INFARMED is competent for, is meant to remove the limit of exercise of the prior existing right of economic private initiative, which is constitutionally established - Article 14(1), 15(1)e 23(1), of Decree-Law No 176/06 of 30 August and Article 61 of the Portuguese Constitution.

III. The Directorate-General of the Economic Activities (DGEA) is responsible for the Public Selling Price (PSP), and the owners of the marketing authorization, when it comes to generics, must formulate their proposal of prices, subject to tacit authorization, 45 days after the submission of the request, notwithstanding eventual suspensions in case of request of elements to the applicant. – Article 1(1), 2 and 4, of Ministerial Order No 300/A/07, of 19th of March.

IV. The administrative act of marketing authorizations assumes the nature of a procedure condition, to be triggered by the interested party through the DGEA, for the fixation of PSP - Article 77 (1) and (3), Decree-Law No 176/06 of 30 August and Article 1(1) of Ministerial Order No 300/A/07 of 19 March.

V. The polygonal or multipolar nature of the administrative legal situation of the act of granting of marketing authorizations, justifies the legitimacy of intervention by third parties that own exclusive rights of patents or supplementary protection certificates, of the reference medicinal product, in the authorization procedure for the generic medicinal product and participation control – Article 52 and 53 of the Administrative Procedure Code.

VI. The acts of registry issued by INFARMED regarding marketing authorizations granted in a centralized procedure by a Community entity, concerning generic medicinal products and while the patents or supplementary protection certificates protection upon the active substance of the drug still exist, are a likely cause of the decrease of a turnover and decline of revenues, a probability shown by Article 514(1) of the Civil Procedure Code, which does not demand proof, making unnecessary to bring to the interim action financial proof of the last two or three years, with the purpose of making accountancy projections for operating losses, decreased profits and gains of exercise through them.

- **Administrative Central Court (South) – Public Selling Price and Marketing Authorizations**

Case No 07706/11 of 8 September 2011

Summary:

I. The PSP, like the MA, is related, in a direct and immediate way, with the trading of the generic medicinal product, and are both administrative acts with external effects, which are turned into multipolar administrative procedures.

II. The granting of marketing authorizations must always take into account existing patents which, INFARMED can investigate, as an administrative authority subjected to the existing legal rules in force.

III. The fixation of the PSP, like the granting of marketing authorizations, must comply with all the rules of multipolar administrative procedures, namely what is laid down in Articles 53, 54, and the following articles of the Administrative Procedural Code, the preliminary hearing and prior interests of marketing authorization owners of the same active substance.

IV. The trading of a generic medicinal product, dependent on two administrative acts (PSP and marketing authorizations) always causes damages to the individuals already in the market, especially if it is traded in a system of exclusivity.

V. Suspending the effects of a marketing authorization or a PSP, when there is already an identical medicinal product in the market, does not jeopardize, in principle, the health public interest; the public interest of sparing in financial means can, however, be jeopardized, but it must be concretely claimed and proved.

_1 _2 _

CONTACT DETAILS

www.srslegal.pt

_LISBOA
R. Dom Francisco Manuel de Melo nº21,
1070-085
T +351 21 313 2000
F +351 21 313 2001

_FUNCHAL
Av. Zarco nº2, 2º,
9000-069 Funchal
T +351 29 120 2260
F +351 29 120 2261

_PORTO (*)
R. Tenente Valadim nº215,
4100-479
T +351 22 543 2610
F +351 22 543 2611

1_ CÉSAR SÁ ESTEVES
PARTNER
T. +351 21 313 2000
cesar.esteves@srslegal.pt

2_ ANA MENÉRES
MANGING ASSOCIATE
T. +351 21 313 2030
ana.meneres@srslegal.pt

3_ MARGARIDA BRITO DA CRUZ
LAWYER TRAINEE
margarida.cruz@srslegal.pt

The Curricula of the Key contact lawyers may be consulted at www.srslegal.pt

Sociedade Rebelo de Sousa & Advogados Associados, RL

Em parceria com_
Simmons & Simmons
Veirano Advogados_BRASIL
(*) Andreia Lima Carneiro & Associados
LCF Leg Couns.Firm_ANGOLA
SAL & Caldeira_MOÇAMBIQUE
Amado & Medina_CABO VERDE