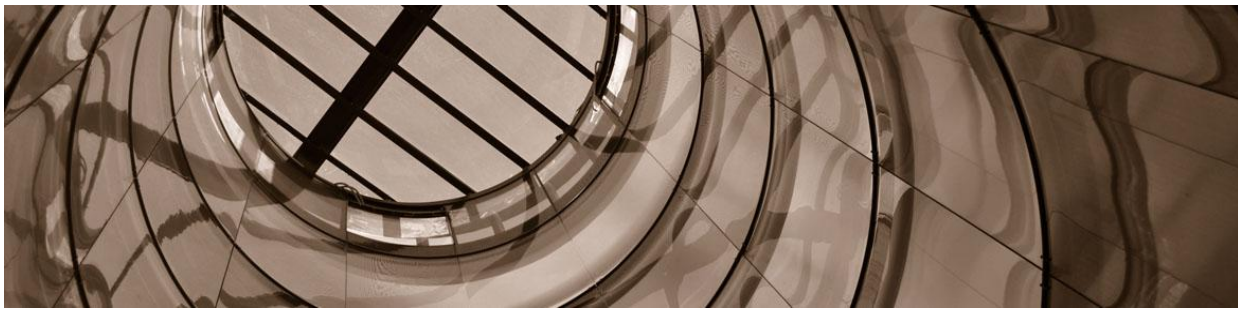
CUATRECASAS, GONÇALVES PEREIRA



NEWSLETTER | HEALTH LAW

NEWSLETTER HEALTH LAW I January – February, 2014

NEWSLETTER HEALTH LAW

I. AMENDMENTS TO THE LEGAL FRAMEWORK OF REIMBURSEMENTS OF MEDICINAL PRODUCTS AND TO THE REGIME OF MEDICINAL PRODUCTS PRICE

The Decree-Law no. 19/2014 ("DL 19/2014") was published last February 5 on the Official Public Gazette ("Diário da República") amending the general scheme of reimbursement by the State in the price of medicinal products, approved by the Decree-Law no. 48-A/2010, of 13th May ("Reimbursement Regime"), and the system of pricing of medicinal products subject to prescription and medicinal products non subject to prescription but reimbursed, approved by the Decree-Law no. 112/2011, of 29th November ("Medicinal Products Price Regime").

The main changes introduced by DL 19/2014, regarding the Reimbursement Regime are the following:

- The main objective of the legislator was to improve the existent regime, by introducing some mechanisms which enable to "understand the real plus of such medicinal products that justify the reimbursement by the Portuguese State". In this respect, the main changes to this legal regime are related to the evaluation proceedings of the medicinal products, either on the phase regarding the grant of the reimbursement, or in the evaluation phase of the reimbursement;

- Regarding the proceeding to obtain the reimbursement on the evaluation phase of the medicinal products, the new regime states expressly that the MAH shall demonstrate the efficiency and/or the relative effectiveness and the higher or equal therapeutic comparative value, presenting to Infarmed the evidence that is now listed in an annex to the Contribution Regime. This annex identifies the criteria which shall be observed either on evaluation or in the revaluation of the medicinal products, which are not only technical and scientific, but also related to the demonstration of an economic benefit, being the evaluation always realized in a comparative way, which means, with reference to characteristics of alternative therapeutic made available.

-Also, under the evaluation proceedings of reimbursement revaluation, the new legal regime establishes, unequivocally, that the burden of proof on the effectiveness of the medicinal product is up to the MAH, and that the MAH, whenever it is required, shall prove that the medicinal product continue to satisfy the reimbursement requirements, by demonstrating the efficiency and/or the relative effectiveness and the higher or equal therapeutic comparative value, presenting to Infarmed the evidence that is listed in the annex to the Contribution Regime;

- Another relevant change is that the exclusion of the reimbursement of a medicinal product is automatic whenever a pharmaceutical group or sub-group that is excluded from the reimbursable medicinal products list. On this matter, we note that it was recently amendment the list of the pharmaceutical groups that could be reimbursed by

Order 45/2014, of 21 February amending the Annex to Order 924-A/2010 of 17 September;

- Finally, the diploma establishes a limit to the price to the public of the generic medicinal products reimbursable, by establishing that, for purposes of assessment of the economic benefit of the generic, which is achieved by setting a price to the public that is 5% lower than the maximum price of the generic whose request for reimbursement is immediately previous to the one at stake, may not result in setting a price that is 20% lower than the reference medicinal product considered for the pricing regime of generic medical products.

We shall now analyze the main changes introduced in the Medicinal Products Price Regime:

- Under the annual review of pricing procedure, such of the reference medicinal products, as of the generics, incorrect updating of prices by the MAH having regard to the rules applicable to annual review implies for the MAH the obligation to transfer to the NHS budget authority the amount equivalent to the difference between the price reported by those entities and the price fixed by Infarmed, for all packages which have been marketed within the NHS with an incorrect price value;

- However, the main novelty of Decree-Law no. 19/2014 of 5 February, and perhaps the most controversial one, is the change to the marketing margins of medicinal products by wholesalers and pharmacies. As the Government had already announced at the end of the year 2013, upon approval by the Council of Ministers of the changes to these legal regimes, it is intended "a greater appreciation of the fixed component over the variable component." Indeed, all levels of prices of the medicinal products foreseen in article 11 of the Medicinal Products Price Regime shall now be composed by a fixed component and the variable component was subjected to a substantial reduction. With the new legal regime, variable components of wholesale margins suffer, on average, a decrease of eight percentage points, and pharmacies suffer, on average, a reduction of 20 percentage points.

- Finally, and although it is not yet regulated, it is expected the implementation of measures to encourage the supply generics through an additional remuneration to the pharmacies.

II. PRIVATE HEALTH CARE UNITS: NEW TYPES OF HEALTH CARE UNITS

The Legal Regime of Private Health Units, regulated by Decree-Law no. 279/2009 of 6 October, that establishes the legal framework regarding the opening, modification and operation of private health care units with or without profit, determines that the listing of the types of private health services units to be approved by the member of the Government responsible for the health sector.

Indeed, since the entry into force of the Legal Regime of Private Health Units there have been published several ordinances establishing minimum requirements for operation and organization of each type of health care units, such as clinics or dental offices (Ordinance no. 268/2010 of 12 May), units of medical and nursing services in obstetrics and neonatology (Ordinance no. 615/ 2010 of 3 August), units exercising nursing practice (Decree no. 801/ 2010) units of physical medicine and rehabilitation activities pursuing diagnostic, therapeutic, family and socio-professional reintegration (Ordinance no. 1212/ 2010), clinics and doctors' offices (Ordinance no. 287/ 2012), private units with ambulatory surgery (Ordinance no. 291/ 2012), private units which have as their object the provision of health services and which have inpatient (Ordinance no. 290/ 2012) and private dialysis units to continue therapeutic activities within the hemodialysis and other debugging techniques like extracorporeal or chronic peritoneal dialysis (Ordinance no . º 347/2013).

Last February 12 three orders were published, under which the requirements have been approved for the organization and operation of three new types of health care unites, namely:
- Private health units of nuclear medicine (Ordinance no. 33/2014, of 12 February);
- Units of private health services radiotherapy/radioncology (Ordinance no. 34/2014, of 12 February) and
- Units of private health services of radiology (Ordinance no. 35/2014, of 12 February).

The units of this type of private health care services that are in operation at the date of publication of the said Ordinances have a period of 2 years to adapt to the new requirements described therein.

Finally, we note that it was also published Order 8/2014 of 14 January, which amends the requirements for operation and organization of private units which have as their object the provision of medical services and nursing obstetrics and neonatology, which are provided for in Order 615/2010 of 3 August. The units already licensed under the said Ordinance have a period of 1 year to adapt to the new requirements of the new ordinance.

III. NATIONAL LEGISLATION

Medicinal Products
Order 251/2014. D.R. 4, Series II of 2014-01-07
Ministry of Health - Office of the Secretary of State for Health
Amends the Annex to the Order 280/2011, of 11th March, which defined the conditions of use and waiver of prescribed opioid medicinal products for the treatment of moderate to strong chronic non-malignant pain.

Order 706-B/2014. D.R. 10, 2º Supplement, Series II of 2014-01-15
Ministry of Health - Office of the Secretary of State for Health
Amends the Annex to the Order 4466/2005, of 10th February, which defined the conditions of use and waiver of prescribed medicinal products for Crohn's Disease patients.

Order 1261/2014. D.R. 18, Series II of 2014-01-27
Ministry of Health - Office of the Secretary of State for Health
Determines that the medicinal products for the treatment of hyperphenylalaninemia (HPA) in patients with phenylketonuria (PKU) and in patients with tetrahydrobiopterin deficiency (BH4) enjoy special subsidy scheme and establishes guidelines in remission.

Order 1261/2014. D.R. 18, Series II of 2014-01-27
Ministry of Health - Office of the Secretary of State for Health
Approves the pharmacotherapeutic medicinal products classification. Revokes Order 21844/2004, of 12th October.

Invoices' Conference Centre
Resolution 20/2014. D.R. 6, Series II of 2014-01-09
Ministry of Health – Health System Central Administration, IP
Creates the Invoices' Conference Centre Management Unit.

Private Health Units
Order 8/2014. D.R. 9, Series I of 2014-01-14
Ministry of Health
First amendment to Order 615/2010, of 3rd August, establishing minimum requirements regarding the organization and operation, human resources and technical facilities for the activity of private health units with the aim of providing medical and nursing services in obstetrics and neonatology.

Order 33/2014. D.R. 30, Series I of 2014-02-12
Ministry of Health
Establishes minimum requirements regarding the organization and operation, human resources and technical facilities for the activity of health units for nuclear medicine.

Order 34/2014. D.R. 30, Series I of 2014-02-12
Ministry of Health
Establishes minimum requirements for organization and operation, human resources and technical facilities for the activity of radiotherapy/radio-oncology private health units.

Order 35/2014. D.R. 30, Series I of 2014-02-12
Ministry of Health
Establishes minimum requirements for organization and operation, human resources and technical facilities for the activity of radiology health units.

National Health Service
Decree-Law 14/2014. D.R. 15, Series I of 2014-01-22
Ministry of Health
Establishes the legal framework of incompatibilities of members of committees, working groups, panels of pre-contractual procedures, and consultants who support the panels, or participate in the selection, evaluation, issuing of standards and guidelines of clinical character, development forms, relating to medicinal products and medical device within the institutions and services of the National Health Service, regardless of their legal nature, as well as the services and bodies of the Ministry of Health.

Order 1317-B/2014. D.R. 18, 3º Supplement, Series II of 2014-01-27
Ministry of Health - Office of the Secretary of State for Health
Establishes a generic authorization quota regarding a maximum number of hours for the hiring of medical personnel, in the provision of services system, by the institutions of the National Health Service in the public business sector.

Order 20/2014. D.R. 20, Series I of 2014-01-29
Ministry of Health
Approves the tables of prices that are to be practiced by the National Health Services, as well as its Regulation, and revokes Order 163/2013 of 24th April.

Order 2156-B/2014. D.R. 28, Supplement, Series II of 2014-02-10
Ministry of Health – Minister's Office
Approves the template for declaration of absence incompatibilities of members of committees, working groups, panels of pre-contractual procedures and consultants who support the panels, or participate in the selection, evaluation, issuing of standards and guidelines of clinical character or development of forms, relating to medical products and medical device within the institutions and services of the National Health Service, regardless of their legal nature, as well as the services and bodies of the Ministry of Health.

Dentistry
Order 1136/2014. D.R. 16, Series II of 2014-01-23
Ministry of Health - Office of the Secretary of State for Health
Creates and determines the composition of the National Medicinal Products Commission and Health Products within the scope of dentistry.

Reimbursement of Medicinal Products
Order 24/2014. D.R. 22, Series I of 2014-01-31
Ministry of Health
First amendment to Order 193/2011 of 13th May, that regulates the payment procedure of State subsidies in the retail price of medicinal products, which is exempt to the beneficiaries of the National Health Service that are not covered by any subsystem, or that receiving reimbursement under the complementarity system.

Order 158/2014. D.R. 37, Series II of 2014-02-21
Ministry of Health - Office of the Secretary of State for Health
Revises the special reimbursement system for medicinal products for the treatment of hepatitis C. Revoked Order 194/2012, of 18th April.

Order 45/2014. D.R. 37, Series I of 2014-02-21
Ministry of Health
Fifth amendment to order 924-A/2010 of 17th September, which defines the pharmacotherapeutic groups and subgroups that integrate the different levels of reimbursement the State in the price of medicinal products. It rectified, by Statement of Rectification 11-A/2014, the inaccuracies of Ordinance 45/2014.

Non-conventional Therapy
Order 25/2014. D.R. 23, Series I of 2014-02-03
Ministry of Health
Establishes the powers and rules for the Non-conventional Therapies Advisory Council.

Transplants
Order 1886/2014. D.R. 26, Series II of 2014-02-06
Ministry of Health - Office of the Deputy Secretary of State for Health
Determines the amounts to be allocated to public or private establishments, including entities located in the Autonomous Regions of the Azores and Madeira, that are authorized to perform acts of harvesting and transplanting. Revokes Order 10485/2011, D.R. 159, Series II, of August 19th 2011.

Integrated Continuous Care
Order 1981/2014. D.R. 27, Series II of 2014-02-07
Ministry of Health - Office of the Deputy Secretary of State for Health
Creates the Working Group for the contracting development of within the integrated continuous care.

Public Procurement Contracts
Order 2521/2014. D.R. 33, Series II of 2014-02-17
Ministry of Health - Office of the Secretary of State for Health
Establishes arrangements within the Ministry of Health's Shared Services regarding the Public Procurement Contracts, which determine the supply conditions for Operating Room Disposable Material - PART III.

Order 2644/2014. D.R. 34, Series II of 2014-02-18
Ministry of Health - Office of the Secretary of State for Health
Establishes arrangements within the Ministry of Health's Shared Services for the Public Procurement Contracts that determine the supply conditions of vaccines and tuberculin.

Statutes of the Order of Nurses
Law 8/2014. D.R. 36, Series I of 2014-02-20

Parliament
Amends the terms of the transitional arrangements for allocating the nurse title, (first amendment to Law 111/2009 of 16th September, that represents the first amendment to the Statute of the Order of Nurses, approved by Decree-Law 104/98 of 21st April) applying the system provided by paragraph 2 of Article 4 of Law 111/2009 to students who graduate in Nursing before the entry into force of the Statute of Nurses reviewed pursuant to the provisions of Law 2/2013 of 10th January and revokes paragraph 4 of article 4 of Law 111/2009.

Military Health System
Order 2943/2014. D.R. 37, Series II of 2014-02-21
Ministry of National Defense – Minister's Office
Reform of the Military Health System.

IV. CASE LAW

Judgment of the South Central Administrative Court of 23 January 2014
Case no. º 10564/13

APIFARMA appealed to the South Central Administrative Court of the sentence upheld the dilatory exception of active illegitimacy of injunction suspending the effectiveness of the rules contained in paragraphs 1, 2, 3, 4, 5 and 6 of Order 4294 -A/2013, of 20 May which led to a 15% reduction in the maximum retail selling prices of reagents (test strips) to determine glycemia, ketonemia and ketonuria and needles, syringes and lancets for people with diabetes. Indeed, according to the sentence, APIFARMA has no legitimacy in court to take individual rights and legally protected interests of its members or of interest in acting for members they are not specifically identified.

APIFARMA has claimed that the rules contained in the order, by their nature, affect the legal rights of its the members, preventing them to continue to charge whatever prices they had practiced before its entry into force, causing current and future damages. For that, the elimination of these rules in the legal system and the suspension of their effectiveness, will allow members of APIFARMA back to practicing prices than previously practiced.

The judgment under review came to agree with APIFARMA to conclude that this is a legitimate party to defend the collective interests of its members, and to collectively defend the individual interests of its members operating in the market covered by those provisions, and consequently agreed with the appeal by the revocation of the contested judgment and ordering the suspension of effectiveness of the rules contained in paragraphs 1, 2, 3, 4, 5 and 6 of Order 4294-A/2013, 20 May.

V. INFARMED

Transparency and Advertising
Information Circular no. º 012/CD/8.1.6 of 2014-01-17
Infarmed clarifies the following:
- Pursuant to paragraph 5 of Article 159 of the Medicinal Products Act, legal entities will also be required to declare to the Communications Platform - Transparency and Publicity any kind sponsorship granted to individuals, including health professionals from January 22, 2014.
- Moreover, under paragraph 7 of that Article 159 of the Medicinal Products Act, it is not necessary to communicate in the Communications Platform - Advertising Transparency salaries and other regular and periodic payments, in cash or in kind, that individuals receive from a single entity when those benefits come from dependent or independent labor, provided they correspond to 80% or more of the total annual value of the proceeds of their work.

Discount Program
Information Circular no. º 013/CD/.8.1.6 of 2014-01-17
Infarmed clarifies the following:
- The discount programs involving a discount in the price of medicinal products, including through the use of discount card, granted by pharmaceutical companies to users (the general public) are not legally allowed.
- The rebates granted by pharmaceutical companies to pharmacies within the circuit of the medicinal products, made in an universal way, in respect of a medicinal product in the context of its commercial relations are accepted and are excluded from the rules governing the advertising of medicinal products.
- Discounts to users can only be made by pharmacies, observing the principle of equality, in the terms set forth in article 5 º and subparagraph d) of paragraph 1 of Article 28 of Decree - Law no 307/2007 , of 31 August, in its current version , and numbers 3 and 4 of Article 3. Decree- Law n . 112/ 2011 of 29 November.

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