The Palliative Care Law

The Palliative Care Law was published in the Official Gazette, on 5 September 2012 – Law No 52/2012.

The increase of longevity and the number of people suffering of chronic diseases and depending of healthcare is an unsurpassable reality. The role of palliative care units becomes more important as providers of specific healthcare adequate to the population's growing needs.

Presently, the majority of the Portuguese die of chronic and long-term diseases, and 60% die in hospitals which, in most cases are not prepared to receive and treat life-ending patients in an adequate way.

The Palliative Care Law will rule the access to palliative care by the citizens, defining the State's responsibility regarding palliative care and creates the National Network of Palliative Care (RNCP), operating under the supervision of the Ministry of Health.

The Law establishes the principles governing palliative care and establishes the patients' rights and those of their families, as well as the respective duties.

Palliative cares shall be provided by the services and facilities of the NHS, and may also be provided by the entities of the social or private sector, whenever the public offer is not adequate.

Pursuant to this Law, the Ministry of Health must (i) approve the national policy regarding palliative care, and promote, follow, supervise the respective implementation, for which he shall be liable for (ii) ensure that palliative healthcare is rendered through a public network for inpatients and outpatients within the NHS and (iii) enter into agreements, within RNCP, for the provision of palliative care with entities of the social or private sector, guaranteeing their supervision and covering effectively the entire national territory.

The National Network of Palliative Care established this Law will be coordinated by a National Commission of Palliative Care operating on the national level, in articulation with the regional and local structures. This Law also established that the operations of the units and teams of palliative care will entail the access by patients to medicinal products considered essential by the World Health Organization (WHO) for the treatment of patients in palliative care.

Palliative care units, intra-hospital and community support teams in palliative care already existing, as well as other facilities and identical services within the National Network of Continuing and Integrated Care, will be included in RNPC.

The Law will enter into force on January 1, 2013.

Presently, the public expenditure associated with chronic diseases represents 60-80% of the total Health budget. The creation of RNCP is aimed at reducing the costs connected with these diseases, as well as to support more than 60.000 Portuguese citizens needing support.

I. NATIONAL LEGISLATION

Functioning of Retail Pharmacies

Ministerial Order No 277/2012, published in the Official Gazette, 1 Series, Number 177, of 12 September 2012 – Defines the standard opening hours of retail pharmacies, rules the approval, the duration, execution, disclosure and supervision of the shifts schedules of the pharmacies, as well as the maximum amount to be charged by shift pharmacies for dispensing medicinal products not prescribed through a medical prescription of the same day or of the day before, and revokes Ministerial Order No 31-A/2011 of 11 January.

Activities of Clinics and Medical Practices

Ministerial Order No 278/2012, published in the Official Gazette, 1 Series, Number 183, of 20 September 2012 – Establishes the minimum requirements applicable to the organization and functioning, human resources and technical installations for clinic and medical practices.

Private Units of Health Care Providence

Ministerial Order No 290/2012, published in the Official Gazette, 1 Series, Number 185, of 24 September 2012 – Establishes the minimum requirements applicable to the organization and functioning, human resources and technical installations of health care institutions with in-patients.

- Pharmacies Licensing

Ministerial Order No 352/2012, published in the Official Gazette, 1 Series, Number 210, of 30 October 2012 – Rules the procedure to be followed to obtain the licensing of new pharmacies, as well as the transfer of location and the transfer in the license, and revokes Ministerial Order No 1430/2007 of 2 November.

II. LEGISLATION OF THE EUROPEAN UNION

- Transplant of Human Organs

Commission Implementing Directive 2012/25/EU, published in the Official Journal of the European Union of 10 October 2012 – Lays down information procedures for the exchange, between Member States, of human organs intended for transplantation, establishing namely (i) procedures for the transmission of information on organ and donor characterization, (ii) procedures for the transmission of the necessary information to ensure the traceability of organs and (iii) procedures for ensuring the reporting of serious adverse events and reactions.

- Farmacovigilance

Directive 2012/26/EU of the European Parliament and the Council, published in the Official Journal of the European Union of 27 October 2012 – Amends Directive 2001/83/EC as regards pharmacovigilance, taking into consideration the need for an automatic procedure at Union level in cases of specific safety issues to ensure that a matter is assessed and addressed in all Member States where the medicinal product is authorized.

II. INFARMED

- Proof of Medical Prescription

Information Note No 213/CD/8.1.6., of 4 October 2012 – To avoid situations where the patients deliver to the pharmacies a medical prescription of a non-reimbursed medicinal product or which does not follow the adequate template for the reimbursement, and the pharmacies dispense the medicinal product without keeping any proof of the prescription, the Infarmed decided that (i) the pharmacies must keep in their paper or electronic archive, the original or the copy of the prescription of the non-reimbursed medicinal products sold and (ii) whenever medicinal products subject to medical prescription are requested without the presentation of the respective medical prescription, the pharmacies must justify that fact and keep a record of those justifications to be presented, if required, in an inspection.

- Software Qualified as Medical Device

Information Note No 214/CD/8.1.7., of 8 October 2012 – Informs that the qualification and classification of *software* as a medical device was discussed in the document "*Guidelines on the qualification and classification of stand alone software used in healthcare within the regulatory framework of medical devices*". According to these Guidelines, the software itself is qualified as a medical device, when it is specifically meant by its manufacturer to be used for one or several medical purposes established in the definition of medical device. Its final purpose must be dully justified by scientific data, including clinical data. However, this issue is still being discussed at the European level.

- Recognition of Marketing Authorization's Request

Information Note No of 12 October 2012 – Infarmed published a group of FAQ's concerning the recognition of the evaluation of marketing authorization applications submitted under the national procedure, taking into account Information Note No 70/CD of 20 March 2012.

- List of Medical Devices of Risk Class III

Information Note No 223/CD/8.1.6., of 22 October 2012 – Infarmed publishes the list of Medical Devices of Risk Class III, which includes the information validated by Infarmed, resulting from the wholesale distributors' records of medical devices, done by wholesale distributors of medical devices, available at Infarmed's site.

- Expiry of Reimbursements - October 2012

Information Note No 106/CD, of 7 July of 2010 - The Infarmed publishes the final List of medicinal products regarding which it was decided the expiry of the reimbursement, as a result of the lack of marketing, during October 2012.

II. ACSS - NHS Centralised Purchases Authority

- Hospital Code of the Medicinal Products

Information Note No 24 of 14 September 2012 – Report of information regarding medicinal products included in the National Hospital Code of the Medicinal Product disaggregated by supplier.

V. COMUNICATIONS – European Documents

- Concentration Watson/Actavis

Communication 2012/C 271/07, of the European Commission, published in the Official Journal of the European Union of 8 September 2012 - Prior notification of a concentration (Case COMP/M.6613 — Watson/Actavis).

- Concentration Louis Dreyfus Commodities Suisse/Ecoval Holding BV

Communication 2012/C 275/03, of the European Commission, published in the Official Journal of the European Union of 12 September 2012 - Non-opposition to a notified concentration (Case COMP/M.6660 — Louis Dreyfus Commodities Suisse/Ecoval Holding BV.

- Concentration EQT VI/BSN Medical

Communication 2012/C 286/05, of the European Commission, published in the Official Journal of the European Union of 22 September 2012 - Non-opposition to a notified concentration (Case COMP/M.6560 — EQT VI/BSN Medical).

- Concentration Procter & Gamble/Arbora

Communication 2012/C 286/08, of the European Commission, published in the Official Journal of the European Union of 22 September 2012 - Non-opposition to a notified concentration (Case COMP/M.6678 — Procter & Gamble/Arbora).

- Marketing Authorizations (EU) – August

Communication 2012/C 293/01, of the European Commission, published in the Official Journal of the European Union of 28 September 2012 - Summary of European Union decisions on marketing authorizations in respect of medicinal products from 1 August 2012 to 31 August 2012*(Published pursuant to Article 13 or Article 38 of Regulation (EC) No 726/2004 of the European Parliament and of the Council).*

Communication 2012/C 293/02, of the European Commission, published in the Official Journal of the European Union of 28 September 2012 - Summary of European Union decisions on marketing authorizations in respect of medicinal products from 1 August 2012 to 31 August 2012*(Decisions taken pursuant to Article 34 of Directive 2001/83/EC or Article 38 of Directive 2001/82/EC).*

- Prices of Medicinal Products for Human Use

Opinion of the European Economic and Social Committee (2012/C 299/15), published in the Official Journal of the European Union of 4 October 2012 - On the *'Proposal for a directive of the European Parliament and of the Council relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems'*.

- Concentration Sun Capital/Rexam Personal and Home Care Packaging

Communication 2012/C 300/12, of the European Commission, published in the Official Journal of the European Union of 5 October 2012 - Prior notification of a concentration (Case COMP/M.6665 — Sun Capital/Rexam Personal and Home Care Packaging Business).

- Investing in Health

Announcement of the European Commission (2012/C 310/05), published in the Official Journal of the European Union of 13 October 2012 - Call for expressions of interest in membership in the multisectoral and independent expert panel to provide advice on effective ways of investing in health.

- Concentration Procter & Gamble/Teva Pharmaceuticals OTC II

Communication 2012/C 314/12, of the European Commission, published in the Official Journal of the European Union of 18 October 2012 - Prior notification of a concentration (Case COMP/M.6705 — Procter & Gamble/Teva Pharmaceuticals OTC II).

- Marketing Authorizations (EU) – September

Communication 2012/C 328/01, of the European Commission, published in the Official Journal of the European Union of 26 October 2012 - Summary of European Union decisions on marketing authorizations in respect of medicinal products from 1 September 2012 to 30 September 2012*(Published pursuant to Article 13 or Article 38 of Regulation (EC) No 726/2004 of the European Parliament and of the Council).*

Communication 2012/C 328/02, of the European Commission, published in the Official Journal of the European Union of 26 October 2012 - Summary of European Union decisions on marketing authorizations in respect of medicinal products from 1 September 2012 to 30 September 2012*(Decisions*

taken pursuant to Article 34 of Directive 2001/83/EC or Article 38 of Directive 2001/82/EC).

VI. EUROPEAN CASE-LAW

- Generic Medicinal Veterinary Product similar to the Reference Medicinal Product

Case C-145/11: Judgment of the Court (Third Chamber) of 19 July 2012 (2012/C 295/16) — European Commission v French Republic

I. Failure of a Member State to fulfill obligations — Infringement of Articles 32 and 33 of Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ 2001 L 311, p. 1) — Decentralized procedure for the grant of marketing authorization in more than one Member State — Generic medicinal products similar to the reference medicinal products already authorized — Member State's refusal to approve based on scientific grounds related to the composition of the medicinal product and the choice of pharmaceutical form — Principle of mutual recognition.

II. The Court declares that, by refusing to approve two requests for marketing authorisation of the medicinal veterinary products CT-Line 15 % Premix and CT-Line 15 % Oral Powder in the context of the decentralised procedure provided for by Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products, as amended by Directive 2004/28/EC of the European Parliament of the Council of 31 March 2004, the French Republic has failed to fulfil its obligations under Articles 32 and 33 of that directive.

III. The Court orders the French Republic to pay the costs.

- Parallel Import

Judgment of the Court of 30 March 2012 in Case E-7/11 (2012/C 370/10) — Grund, elli- og hjúkrunarheimili v the Icelandic Medicines Agency (Lyfjastofnun)

I. The national authorities may make importation by a health care institution, such as the Plaintiff, for use by the people in the care of the institution, of medicinal products from Norway which have been granted national marketing authorization in Norway, and which are identical or essentially similar to products which have national marketing authorization in Iceland, subject to a parallel import license.

II. Such a license must be issued under a procedure limited to controlling that the medicinal products in question have a valid marketing authorization in the EEA State of export, and that the product is identical or essentially similar to products having marketing authorization in the EEA State of importation.

III. In this context, the national authorities may not require parallel importers, such as the Plaintiff, to submit manufacturing control reports. Such a practice cannot be justified under Article 13 EEA.

IV. When a medicinal product is not intended to be delivered directly to the patient, the competent authorities' right to grant exemptions under Article 63(3) of Directive 2001/83/EC is limited by the general principles of EEA law. The discretion must not be exercised in a disproportionate, arbitrary or abusive, in particular protectionist, manner.



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