Liabilities Law

On 21 February, was published, in the Official Gazette, Law No 8/2012, laying down the rules applicable to the liabilities undertaken by public entities and the payments in delay, applicable to all the public entities of the National Health Care System (NHS).

This Law has been highly discussed, as it establishes civil, disciplinary, financial, sanctionatory and/or reintegratory and even criminal liability for all of those undertaking liabilities breaching the law. The Law refers specifically to those "holding political or management positions or those responsible for accountancy" and provides them the possibility of producing evidence regarding the absence of misconduct.

Moreover, those in leading or management positions or those responsible for accountancy have the responsibility of guaranteeing that the liabilities undertaken do not exceed the available funds, as established in number 1 of Article 5 of the Law.

The payments are made after such assessment, but only if the law is respected, as well as, the applicable legal requirements regarding execution of expenses, as established in Article 9 of the Law.

This Article adds that 'all of those undertaking liabilities in breach with the rules and procedures provided by the Law are personally and jointly responsible for the damages incurred before the economic agents'.

We may conclude therefore, that whenever a liability is undertaken in breach of the law, not only the responsible person is liable in several ways, but that person will also be liable personally and severally for that act.

In what respects these liabilities, the ACSS (Central Administration of the Health System) refers that 'only the liabilities undertaken in 2012 should be considered new liabilities' and that these are the liabilities that cannot exceed the available funds.

In case there is an exceptional temporary increase of the available funds, an explicit authorization by a member of the Government responsible for the Financial area is required.

The ACSS intends to implement these new rules of budget planning, however, it will be necessary to comply with an adaptation period, as 'it would be unrealistic to assume that the NHS could reduce the average deadlines of payments from 240 days to 90 days in just one year', and is currently discussing a program for the settlement of debts to better comply with this Law.

These measures are based on the liabilities undertaken before the Troika, once it will only authorize the payment of the debt of the Health sector if there is a guarantee that the hospitals will not accumulate more debt.

I. NATIONAL LEGISLATION

Prices of Medicinal Products

Ministerial Order No 3/2012, published in the Official Gazette, 1 Series, Number 1, of 2 January 2012 – Following Article 12 of Decree-Law No 112/2011 of 29th of November, this Ministerial Order authorizes the exceptional revision of the price of the medicinal product (ERP), for reasons of public interest or by initiative of the holder of the marketing authorization, by means of a duly justified decision of the members of the Government responsible for the economic and health sectors.

Ministerial Order No 4/2012, published in the Official Gazette, 1 Series, Number 1, of 2 January 2012 – Establishes the pricing rules of medicinal products, the modifications and annual revision, as well as the respective deadlines.

Exploration of the 'Social Games' assigned to the Ministry of Health

Ministerial Order No 7/2012, published in the Official Gazette, 1 Series, Number 2, of 3 January 2012 – Defines the procedural rules to be complied with, in order to allocate the net profits of the current year, obtained through the exploration of the 'social games' assigned to the Ministry of Health.

Pricing Lists – Institutions and Services integrated in the NHS

Ministerial Order No 19/2012, published in the Official Gazette, 1 Series, Number 15, of 20 January 2012 – Amends the Regulation of the Pricing Lists of the Services and Institutions integrated in the NHS, approved by Ministerial Order No 132/2009 of 30 January.

Approval of Organic Laws

SCAD
Decree-Law No 17/2012, published in the Official Gazette, 1 Series, Number 19, of 26 January 2012 – Approves the organic law of the Service of Intervention in Addicting Behaviours and Dependences.

DGS
Regulatory Decree No 14/2012, published in the Official Gazette, 1 Series, Number 19, of 26 January 2012 – Approves the organic law of the Directorate-General of Health.

ARS
Decree-Law No 22/2012, published in the Official Gazette, 1 Series, Number 21, of 30 January 2012 – Approves the organic law of the Regional Administrations for Health.

INSA
Decree-Law No 27/2012, published in the Official Gazette, 1 Series, Number 28, of 8 February 2012 – Approves the organic law of the National Health Institute Doutor Ricardo Jorge.

SGS

Regulatory Decree No 23/2012, published in the Official Gazette, 1 Series, Number 29, of 9 February 2012 – Approves the organic law of the General-Secretary of the Ministry of Health.

IGAS
Decree-Law No 33/2012, published in the Official Gazette, 1 Series, Number 31, of 13 February 2012 – Approves the organic law of the Health Activities General Inspection.

INEM
Decree-Law No 34/2012, published in the Official Gazette, 1 Series, Number 32, of 14 February 2012 – Approves the organic law of the National Institute of Medical Emergency.

ACSS
Decree-Law No 35/2012, published in the Official Gazette, 1 Series, Number 33, of 15 February 2012 – Approves the organic law of the Central Administration of the Health System.

IPST
Decree-Law No 39/2012, published in the Official Gazette, 1 Series, Number 34, of 16 February 2012 – Approves the organic law of the Portuguese Institute of the Blood and Transplantation.

INFARMED
Decree-Law No 46/2012, published in the Official Gazette, 1 Series, Number 40, of 24 February 2012 – Approves the organic law of the National Authority of Medicinal Products and Health Products.

- Regulated Jobs with Impact on Health

Ministerial Order No 35/2012, published in the Official Gazette, 1 Series, Number 25, of 3 February 2012 – Approves the list of regulated jobs and national authorities that are competent to undertake the recognition of professional qualifications in each job and the list of regulated jobs with an impact on health which do not benefit from the automatic recognition system.

- Extinction and Merger – Braga Hospital

Ministerial Order No 40/2012, published in the Official Gazette, 1 Series, Number 30, of 10 February 2012 – Extinguishes Braga District Hospital, and it is merged with the Regional Health Administration of the North.

- Electronic Prescription of Medicinal Products

Ministerial Order No 46/2012, published in the Official Gazette, 1 Series, Number 31, of 13 February 2012 – First amendment to the Ministerial Order No 198/2011, of 18 of May, which establishes the legal framework of electronic prescription of medicinal products. This Ministerial Order establishes that hand-written medical prescriptions will be validated through the introduction of a new model of stamp, issued by the Official Printing Office.

- State Budget

Decree-Law No 32/2012, published in the Official Gazette, 1 Series, Number 31, of 13 February 2012 – Establishes the rules for the execution of the State Budget for 2012 and will be extended to the institutions of the NHS as well, specially in respect to the undertaking of liabilities by those in leading positions, managers and people responsible for accountancy, which cannot exceed the available funds (article 84 of the Decree-Law) and the personal and jointly liability that they are subjected to, in case the liabilities undertaken by them are in breach with the law (article 88 of the Decree-Law).

- Extinction and Merger – Curry Cabral and Alfredo da Costa Maternity

Decree-Law No 44/2012 published in the Official Gazette, 1 Series, Number 39, of 23 February 2012 – Extinguishes Curry Cabral Hospital and Alfredo da Costa Maternity and merges both with Hospital of Central Lisbon.

II. EUROPEAN COMMISSION - COMMUNICATIONS

- Concentration Saria/Teeuwissen/Jagero II/Quintet/Bioiberica

Communication 2012/C 12/07, of the European Commission, published in the Official Journal of the European Union of 14 January 2012 - Prior Notification of a Concentration (Case COMP/M.6438 — Saria/Teeuwissen/Jagero II/Quintet/Bioiberica).

- Concentration Senoble/Agrial/Senagral JV

Communication 2012/C 19/06, of the European Commission, published in the Official Journal of the European Union of 24 January 2012 - Prior Notification of a Concentration (Case COMP/M.6441 — Senoble/Agrial/Senagral JV).

- Concentration Unilever/Sara Lee Body Care – Legal Opinion

Communication 2012/C 23/08, of the European Commission, published in the Official Journal of the European Union of 28 January 2012 – Opinion of the Advisory Committee on mergers given at its meeting of 5 November 2010 concerning a preliminary draft decision relating to Case COMP/M.5658 — Unilever/Sara Lee Body Care.

- Food for Medical Purposes

Communication 2012/C 24/26, of the European Commission, published in the Official Journal of the European Union of 28 January 2012 – Opinion of the European Economic and Social Committee on the 'Proposal for a regulation of the European Parliament and of the Council on food intended for infants and young children and on food for special medical purposes'.

- Radioactive Substances present in the Water

Communication 2012/C 24/27, of the European Commission, published in the Official Journal of the European Union of 28 January 2012 – Opinion of the European Economic and Social Committee on the 'Proposal for a Council directive laying down requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption'.

- Concentration Oaktree/Panrico

Communication 2012/C 27/01, of the European Commission, published in the Official Journal of the European Union of 1 February 2012 – Non-opposition to a notified concentration (Case — COMP/M.6430 Oaktree/Panrico).

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

Communication 2012/C 33/02, of the European Commission, published in the Official Journal of the European Union of 7 February 2012 – Non-opposition to a notified concentration (Case — COMP/M.6091 — Galenica/Fresenius Medical Care/Vifor Fresenius Medical Care Renal Pharma JV).

- Commission's Legislative Proposals

Communication 2012/C 37/03, of the European Commission, published in the Official Journal of the European Union of 10 February 2012 – Relates to the Legislative Proposals adopted by the Commission:

COM (2011) 633 of 11.10.2011 – Amended proposal for a Directive of the European Parliament and of the Council amending Directive 2001/83/EC, as regards information to the general public on medicinal products subject to medical prescription and as regards pharmacovigilance.

COM(2011) 634 of 11.10.2011 - Amended proposal for a Regulation of the European Parliament and of the Council amending Council Regulation (EC) No 1290/2005 and Council Regulation (EC) No 1234/2007 as regards distribution of food products to the most deprived persons in the Union.

- Marketing Authorizations List

Communication 2012/C 44/05, of the European Commission, published in the Official Journal of the European Union of 16 February 2012 – Standing Committee of the EFTA States - List of marketing authorisations granted by the EEA EFTA States for the first half of 2011 regarding medicinal products.

Communication 2012/C 56/01, of the European Commission, published in the Official Journal of the European Union of 24 February 2012 – Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 November 2011 to 31 December 2011*(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 56/02, of the European Commission, published in the Official Journal of the European Union of 24 February 2012 – Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 November 2011 to 31 December 2011*(Decisions taken pursuant to Article 34 of Directive 2001/83/EC or Article 38 of Directive 2001/82/EC).*

- Concentration Ravago/Barentz Europe/JV

Communication 2012/C 59/09, of the European Commission, published in the Official Journal of the European Union of 22 February 2012 – Re-notification of a previously notified concentration (Case COMP/M.6500 — Ravago/Barentz Europe/JV) — Candidate case for simplified procedure.

III. INFARMED

- Notification of Cosmetics

Information Note No 003/CD of 10 January 2012 – Since 11 of January 2012, those responsible for the placement of cosmetics on the market of the European Union can notify their products in the Notification of Cosmetics Portal (CPNP), which will be made available by the European Commission. During the transitional period, since 11/01/2012 until 10/07/2013, cosmetic products which are not notified through the CPNP must be notified to CIAV and Infarmed by those responsible for their placement in the market.

- Expiry of Reimbursements (January 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 January 2012.

- Hydrocortisone – Authorization of Use

Information Note No 017/CD of 25 January 2012 – Following the stock rupture of the medicinal product *Hydrocortisone*, the Infarmed authorized the special utilization of two similar medicinal products marketed in other European Union countries.

- Prior Evaluation of Medicinal Products subject to Medical Prescription acquired by NHS Hospitals

Information Note No 019/CD of 30 January 2012 – The Infarmed considers that, if a medicinal product is to be financed by the NHS, it should have been previously evaluated according to Decree-Law No 195/2006, which establishes a mandatory prior evaluation of new medicinal products reserved exclusively for treatments inside the hospital and other medicinal products

subject to restricted medical prescription or to Decree-Law No 48-A/2010 which establishes the State reimbursement regime regarding the price of medicinal products prescribed to the patients of the NHS.

- New Template Authorization for the Exercise of the Activity of Wholesale Distribution of Medicinal Products for Human Use

Information Note No 020/CD of 1 February 2012 – Following the publication of Directive 2011/62/CE of the European Parliament and the Council, of 8 June 2011, a community template for the authorization of wholesale distribution of medicinal products for human use is adopted aiming to ensure transparency and the reliability of the supply chain.

- European Common Platform of Submission

Information Note No 025/CD of 7 February 2012 – The evolution and development of project CESP to undertake a new test with a wider concept was approved, jointly with Infarmed. This test of 'concept' was initiated on 6 February and will continue until June 2012, when it is expected a definitive decision regarding the development of CESP by the Agency Chiefs.

- Access to Medicinal Products in the Hospital

Information Note No 023/CD of 8 February 2012 – Infarmed clarifies some doubts with respect to the access to medicinal products provided by the pharmaceutical services of the NHS Hospitals, namely concerning the special reimbursement regimes.

- Implementation of New European Legislation on Pharmacovigilance

Information Note No 034/CD of 15 February 2012 – In what concerns the new European legislation on pharmacovigilance, published in December 2010, the European Medicines Agency recently released a detailed plan of the implementation of this legislation group.

- Expiry of Reimbursements (February 2012)

Through nº1 of 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 February 2012.

IV. ACSS - NHS Centralised Purchases Authority

- Patients Moderating Fees

Informative Note No 1 of 3 January 2012 – Request for recognition of Economic Insufficiency for exemption of Payment of the Patients Moderating Fees.

Regulation No 4 of 12 January 2012 – Transitional period for the implementation of the new Patients Moderating Fees regime.

Regulation No 5 of 12 January 2012 – Means of evidence to obtain the exemption of payment of Patients Moderating Fees for patients with an incapacity level of 60%.

Regulation No 7 of 19 January 2012 – Exemption of the payment of the Patients Moderating Fees concerning the system of Justice Administration.

Regulation No 8 of 19 January 2012 – Means of evidence to obtain the exemption of payment of Patients Moderating Fees for blood donors.

Regulation No 12 of 30 January 2012 – Exemption of payment of Patients Moderating Fees in case of oncology diseases.

Informative Note No 6 of 30 January 2012 – Exemption of payment of Patients Moderating Fees related to medical appointments, hospital day sessions, or other necessary complementary acts adding to them, in the context of Mental Health.

Informative Note No 7 of 30 January 2012 – Exemption of payment of Patients Moderating Fees related to medical appointments on family planning and complementary acts adding to them.

Informative Note No 8 of 30 January 2012 – Application of the State Budget Law for 2012 – payment of extra work.

V. EUROPEAN CASE-LAW

- Supplementary Protection Certificate for Medicinal Products

Communication 2012/C 25/17 of 28 January

Case C-322/10: Judgment of the Court (Fourth Chamber) of 24 November 2011 (reference for a preliminary ruling from the Court of Appeal (England and Wales) (Civil Division) — United Kingdom) — Medeva BV v Comptroller General of Patents, Designs and Trade Marks

I. Reference for a preliminary ruling — Court of Appeal (England and Wales) (Civil Division) — Interpretation of Article 3(a) and (b) of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (OJ 2009 L 152, p. 1) — Conditions for obtaining a certificate — Concept of a 'product protected by a basic patent in force' — Criteria — Whether there exist further or different criteria for a medicinal product comprising more than one active ingredient or for a multi-disease vaccine.

II. Article 3(a) of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products must be interpreted as precluding the competent industrial property office of a Member State from granting a supplementary protection certificate relating to active ingredients which are not specified in the wording of the claims of the basic patent relied on in support of the application for such a certificate.

III. *Article 3(b) of Regulation No 469/2009 must be interpreted as meaning that, provided the other requirements laid down in Article 3 are also met, that provision does not preclude the competent industrial property office of a Member State from granting a supplementary protection certificate for a combination of two active ingredients, corresponding to that specified in the wording of the claims of the basic patent relied on, where the medicinal product for which the marketing authorisation is submitted in support of the application for a special protection certificate contains not only that combination of the two active ingredients but also other active ingredients.*

- Opening of New Pharmacies

Communication 2012/C 25/34 of 28 January

Case C-315/08: Order of the Court (Seventh Chamber) of 29 September 2011 (reference for a preliminary ruling from the Consiglio di Stato — Italy) — Angelo Grisoli v Regione Lombardia

I. Reference for a preliminary ruling — Consiglio di Stato — Interpretation of Articles 152 and 153 EC — Opening of new pharmacies — National legislation fixing limits on the basis of the number of inhabitants and laying down the conditions for authorising the opening of a new pharmacy.

II. Article 49 TFEU does not preclude national legislation, such as that at issue in the main proceedings, which limits the establishment of new pharmacies by providing that in towns with a population of less than 4 000 inhabitants, only one pharmacy may be set up and *in towns with more than 4 000 inhabitants, the establishment of a new pharmacy is subject to conditions, such as the exceeding by at least 50 % of the number of inhabitants needed for a pharmacy and a minimum distance from already existing pharmacies, on condition that such legislation permits, by way of derogation from its basic rules, the establishment of a sufficient number of pharmacies to guarantee an appropriate pharmaceutical service in areas with special demographic or geographical characteristics, something which it is for the national court to ascertain.*

- Supplementary Protection Certificate for Medicinal Products (II)

Communication 2012/C 32/10 of 4 February

Case C-125/10: Judgment of the Court (Second Chamber) of 8 December 2011 (reference for a preliminary ruling from the Bundespatentgericht — Germany) — Merck Sharp & Dohme Corporation (formerly Merck & Co.) v Deutsches Patent- und Markenamt

I. Reference for a preliminary ruling — Bundespatentgericht — Interpretation of Article 13(1) of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (OJ 2009 L 152, p. 1) — Possibility of granting the certificate if the period of time between the filing of the application for the basic patent and the date of first authorisation for marketing in the Community is shorter than five years.

II. *Article 13 of Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products, as amended by Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006, read in conjunction with Article 36 of Regulation No 1901/2006, must be interpreted as meaning that medicinal products can be the object of the grant of a supplementary protection certificate where the period that has elapsed between the date of lodging the basic patent application and the first marketing authorisation in the European Union is less than five years. In such a case, the period of the paediatric extension provided for by the latter regulation starts to run from the date determined by deducting from the patent expiry date the difference between five years and the duration of the period which elapsed between the lodging of the patent application and the grant of the first marketing authorisation.*

Marketing Authorization of Medicinal Products

Communication 2012/C 32/10 of 4 February

Case T-52/09: Judgment of the General Court of 14 December 2011 — Nycomed Danmark v EMA

I. Medicinal products for human use — Authorisation to place a medicinal product on the market — Regulation (EC) No 1901/2006 — Application for a waiver from the obligation to submit a paediatric investigation plan — Rejection by the EMA — Misuse of powers.

II. Application for annulment of the decision of the European Medicines Agency (EMA) of 28 November 2008 rejecting the applicant's application for a specific waiver with respect to perflubutane in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council, as amended.

III. The Court:

1. *Dismisses the action;*
2. *Orders Nycomed Danmark ApS to bear its own costs and those of the European Medicines Agency (EMA), including those relating to the proceedings for interim measures;*
3. *Orders the Portuguese Republic, the Kingdom of Belgium, the United Kingdom of Great Britain and Northern Ireland, the French Republic and the European Commission to bear their own costs, including those relating to the proceedings for interim measures.*

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