New Clinical Trials Regulation

On 17 July 2012, the Commission adopted a Proposal for a Regulation of the European Parliament and of the Council on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC – Clinical Trials Regulation.

The initiative of revision took place on 10 December 2008, when the European Commission announced, in its Communication on "Safe, Innovative and Accessible Medicines: a Renewed Vision for the Pharmaceutical Sector", that an assessment would be made of the application of the Clinical Trials Directive.

This assessment covered, in particular, various options for improving the functioning of the Clinical Trials Directive with a view to making legislative proposals.

Subsequently, on 9 February 2011, a public consultation on a concept paper on the revision of the 'Clinical Trials (Directive 2001/20/EC) was launched, presenting a 'preliminary appraisal' of which option appeared to be the most suitable one to address some of the key concerns of the Clinical Trials Directive, as well as the main figures used to evaluate the impacts of the different policy options.

Clinical trials as defined in Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 are investigations of medicines in humans where the medicines are applied outside normal clinical practice on the basis of a research protocol. In the EU/EEA, approximately 4 400 clinical trials are applied for every year.

Directive 2001/20/EC has brought about important improvements in the safety and ethical soundness of clinical trials in the EU and in the reliability of clinical trials data. However, the Directive 2001/20/EC has had many direct effects on the cost and feasibility of conducting clinical trials which, in turn, have led to a decline in clinical trial activity in the EU, consequently, the regulatory requirements and consequential costs of the Directive have aggravated other causes (such as salary costs and the need to conduct multinational studies to reach recruitment targets).

Thus, the Commission considered that a revision of the Directive was deemed as necessary, in order to promote the clinical trials activity once again.

The Regulation Proposals establish modifications, namely:

(i) greater collaboration on approval of clinical trials, meaning that the authorities in EU countries would work together and be held to the same timeframe when approving clinical trials, ensuring they are thoroughly and expertly assessed.

(ii) rules for clinical trials based on the actual risk posed to the safety of participants.

(iii) greater openness in clinical trials both within and outside the EU, including more public access to the results, whether positive or negative.

These rules contribute to the protection of patients' rights and safety and ensure data is reliable.

The new Regulation will benefit all the European citizens, once more innovative treatments will be available, using new or existing medicines and will benefit, particularly, the Academic research institutions and the pharmaceutical industry, for they will have clearer rules governing their research into new drugs.

The proposal has been submitted to the European Parliament and the Council, and in case it is approved, it will most likely enter into force in the end of 2016. The Regulation, unlike the Directive, will be immediately applicable in all EU member countries, including in Portugal, not needing a transposition act.

I. NATIONAL LEGISLATION

Organic Law of the National Institute of Intellectual Property

Decree-Law No 147/2012, published in the Official Gazette, 1 Series, Number 134, of 12 July 2012 – Approves the organic law of the National Institute of Intellectual Property (Instituto Nacional de Propriedade Intelectual, I.P. (INPI).

Amendments to the Legal Framework of Medicinal Products Pricing

Decree-Law No 152/2012, published in the Official Gazette, 1 Series, Number 134, of 12 July 2012 – First amendment to Decree-Law No 112/2011 of 29 November, which approves the pricing legal framework of reimbursed medicinal products subject to medical prescription and medicinal products not subject to medical prescription, which came into force on 1 August 2012. This Decree-Law introduces, essentially, the following amendments:

- The Infarmed is, as from 1 August, the competent authority to authorize the Price for Sale to the Public (PSP) of medicinal products subject to medical prescription and reimbursed medicinal products not subject to medical prescription, notwithstanding DGAE's hearing within 10 days;
- The prices authorized by Infarmed are maximum prices for sale;

- The PSP of the reference medicinal products is determined by the average PSP of that medicinal product in the two years prior to the price request of the first generic medicinal product.

Living Will

Law No 25/2012, published in the Official Gazette, 1 Series, Number 136, of 16 July 2012 – Regulates the anticipated health will directives to be followed in case of certain listed health conditions suffered by the person making the will, namely through the form of a living will, and the nomination of a health care attorney and creates the National Registry of the Living Will (Registo Nacional do Testamento Vital (RENTEV).

Human Health Protection

Decree-Law No 154/2012, published in the Official Gazette, 1 Series, Number 136, of 16 July 2012 – Amends the List of active substances which can be included in biocide products, with a view to protect human and animal health and safeguard the environment, transposing Directives No 2011/66/UE, 2011/67/UE, 2011/69/UE, of the Commission, of 1 July, Directives No 2011/71/UE, of the Commission, of 26 July, 2011/78/UE, 2011/79/UE, 2011/80/UE, 2011/81/UE of the Commission, of 20 September and proceeds to the ninth amendment of the Decree-Law No 121/2002, of 3 May.

Organic Law of the National Institute of Legal Medicine

Decree-Law No 166/2012, published in the Official Gazette, 1 Series, Number 147, of 31 July 2012 – Approves the organic law of the National Institute of Legal Medicine (Instituto Nacional de Medicina Legal e Ciências Forenses, I. P.).

Retail Pharmacies

Decree-Law No 171/2012, published in the Official Gazette, 1 Series, Number 148, of 1 August 2012 – Second amendment to Decree-law No 307/2007, of 31 August, which establishes the legal framework of the retail pharmacies.

Decree-Law No 172/2012, published in the Official Gazette, 1 Series, Number 148, of 1 August 2012 – Second amendment to Decree-law No 53/2007, of 31 August, of 8 March, which regulates the opening hours of the retail pharmacies.

Chronic Patient

Parliament Resolution No 102/2012, published in the Official Gazette, 1 Series, Number 151, of 6 August 2012 – Recommends to the Government to create the chronic patient statute and of the national chart of incapacity and functionality of health.

Creuzfeldt-Jakob (vDCJ) Disease

Decree-Law No 185/2012, published in the Official Gazette, 1 Series, Number 148, of 9 August 2012 – Fourth amendment to Decree-Law No 189/2000, of 12 August, adding to List A of Annex II the tests to the variation of the disease Creuzfeldt-Jakob (vDCJ), for blood screening, diagnostic and confirmation, transposing Directive No 2011/100/UE, of the Commission, of 20 December 2011.

Organic Law of the Authority of Food and Economic Security

Decree-Law No 194/2012, published in the Official Gazette, 1 Series, Number 163, of 23 August 2012 – Approves the organic law of Authority of Food and Economic Security (Autoridade de Segurança Alimentar e Económica – ASAE).

Blood Donor

Law No 37/2012, published in the Official Gazette, 1 Series, Number 165, of 27 August 2012 – Statute of the Blood Donor, in force since 28 August 2012, conferring various rights, namely, the patients right to the moderating fees exemption in the access to the SNS services.

II. LEGISLATION OF THE EUROPEAN UNION

Scientific Information

Commission Recommendation of 17 July 2012, published in the Official Journal of the European Union of 21 July 2012 - Commission Recommendation on the access to and preservation of scientific information.

Medicinal Products Pharmacovigilance

Corrigendum to Regulation (EU) No 1235/2010 of the European Parliament and of the Council of 15 December, published in the Official Journal of the European Union of 27 July 2012 – Amends, as regards pharmacovigilance of medicinal products for human use, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, and Regulation (EC) No 1394/2007 on advanced therapy medicinal products.

Cosmetic Products – Adaptation to the Technical Progress

Commission Implementing Directive 2012/21/EU of 2 August 2012, published in the Official Journal of the European Union of 3 August 2012 – Amends, for the purpose of adaptation to technical progress, Annexes II and III to Council Directive 76/768/EEC relating to cosmetic products.

Marketing Authorization Expiry (EU)

Commission Regulation (EU) No 712/2012 of 3 August 2012, published in the Official Journal of the European Union of 4 August 2012 – Amends Regulation (EC)

No 1234/2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products.

- Active Implantable Medical Devices and Medical Devices

Commission Regulation (EU) No 722/2012 of 8 August 2012, published in the Official Journal of the European Union of 9 August 2012 – Concerns particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin.

III. INFARMED

- Expiry of Reimbursements (May 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 July 2012.

- Guidelines for the Evaluation of the Security of the Nanomaterials used in Cosmetic Products

Information Note No 160/CD/8.1.6, of 20 July 2012 – The European Commission published on 6 July of 2012, guidelines for the evaluation of the security of the nanomaterials used in cosmetic products – *Guidance on the Safety Assessment of Nanomaterials in Cosmetics* – which reflect the latest technologic developments on the use of nanomaterials on cosmetic products and intend to facilitate the compliance, by the cosmetic industry (Responsible Person), with the requirements established in article 16 of the Regulation (EC) No 1223/2009, which comes into force on 11 January 2013. Thus, from this date onwards, the Responsible Person will have to notify the European Commission 6 (six) months prior all cosmetic products containing nanomaterials enter into the market, through the European Notification Portal, among other important innovations.

- Adverse Reaction to Medicinal Products – Portal RAM (Infarmed)

Information Note No 162/CD/8.1.6, of 23 July 2012 – Within the context of the new European legislation regarding pharmacovigilance (Directive 2010/84/EU, of 15/12/2010), the Infarmed developed an application – RAM (Adverse Reaction to Medicinal Products) Portal – which facilitates and also makes faster the notification of the suspect of adverse reactions to medicinal products (RAM) by health professionals, and simultaneously, integrate the users in the National System of Pharmacovigilance, which is available since 23/07/2012, through Infarmed's *website*.

- Price for Sale to the Public (PSP) Authorization

Information Note No 166/CD/8.1.6, of 27 July 2012 – After the publication of Decree-Law No 152/2012, of 12 July, the Infarmed, as from 1 August 2012, is the competent entity to authorize the Price for Sale to the Public (PSP) of the reimbursed medicinal products subject to medical prescription and the medicinal products not subject to medical prescription. Thereby, the Infarmed published, on its website, regarding this new competence, several information, namely regarding the request for price approval, the request of exceptional price revisions (REP), notifications of temporary price alterations, price declarations and other additional information.

- Generics Marketing Authorizations Requests – Centralized Procedure

Information Note No 168/CD/8.1.6, of 31 July 2012 – As from 31/07/2012, the Infarmed will publish, on its *web* page, the request of a number of national registry concerning authorized medicinal products by the centralized procedure, with the following elements (i) name of the person requesting the number of the national registry, (ii) date of the request of the number of the national registry, (iii) substance, dosage and pharmaceutical form of the medicinal product and (iv) brand medicinal product.

- Extension of the Amendments Regulation to the National Procedure

Information Note No 190/CD/8.1.6, of 14 August 2012 – The EU Regulation No 712/2012 of the European Commission of 3 August 2012, was published on 4 August 2012, amending the Amendments Regulation (Regulation CE No 1234/2008 of the Commission of 24 November 2008), concerning the analysis of the amendments of the expiry of the marketing authorizations of medicinal products for human use and veterinary medicinal products, establishing, among other alterations, the extension of the Amendments Regulation to the national procedure – since 4 August 2013. The Regulation (EU) No 712/2012 is applicable since 2 November 2012, except article 1º, nº 10, 15, 18, paragraphs a) and c), 21, 22 and 23, which are only applicable as from 4 January 2013.

IV. ACSS - NHS Centralised Purchases Authority

- Patients Moderating Fees

Information Note No 17 of 24 July 2012 – Exemption of the payment of the patients moderating fees for oncological patients.

- Cooperation between Ministry of Health and Autonomous Region of Madeira

Information Note No 18 of 26 July 2012 – Cooperation between the Ministry of Health and the Regional Secretariat for Social Issues of the Government of the Autonomous Region of Madeira.

Information Note No 21 of 31 August 2012 - Cooperation between the Ministry of Health and the Regional Secretariat for Social Issues of the Government of the Autonomous Region of Madeira (RAM): application of the addendum to the cooperation protocol establishing the reciprocity regarding the dispensing of medicinal products.

- National Hospitals Code of Medicinal Products

Regulation No 32 of 18 July 2012 – Reports information regarding the medicinal products registered in the National Hospitals Code of medicinal products, discriminating the suppliers.

- Payment of Health Benefits by the Beneficiaries

Regulation No 33 of 19 July 2012 – Sets the conditions and procedures of payment of the SNS benefits to the beneficiaries of the NHS, public subsystems of the ADSE (Directorate-General of Social Protection of to the Employees and Agents of the Public Administration), SAD from GNR (Health Assistance Division from National Republican Guard), PSP (Public Security Police) and ADM (Health Assistance to the Militaries) from the Army, which must be charged by the health units in the context of the program-contract – Modifying Agreement 2012.

- Liabilities Law

Regulation No 34 of 26 July 2012 – Law No 8/2012 of 21 February – Approves the rules applicable to the amounts to be considered in the available funds, to the undertaking of liabilities and to the delayed payments from the public entities of the NHS (Update II).

V. COMUNICATIONS – European Documents

- Investment in Health

Commission Decision (2012/C 198/06) of 5 July 2012, published in the Official Journal of the European Union of 6 July 2012 - Commission decision on setting up a multisectoral and independent expert panel to provide advice on effective ways of investing in health.

- Products Security

European Parliament resolution (2012/C 199 E/01) of 8 March 2011, published in the Official Journal of the European Union of 7 July 2012 – Resolution on the revision of the General Product Safety Directive and market surveillance.

Commission Implementing Decision (2012/C 204/03) of 11 July 2012, published in the Official Journal of the European Union of 12 July 2012 – Decision on the financing of the 2012 work programme on IT tools in the field of food safety, animal health, animal welfare and plant health.

- Health Inequalities

European Parliament resolution (2012/C 199 E/04) of 8 March 2011, published in the Official Journal of the European Union of 7 July 2012 – Resolution on reducing health inequalities in the EU, recommending several measures to be taken in cooperation with the EU Member States.

- Concentration Lactalis/Skanemejerier

Communication 2012/C 208/02, of the European Commission, published in the Official Journal of the European Union of 14 July 2012 - Non-opposition to a notified concentration (Case COMP/M.6522 — Groupe Lactalis/Skanemejerier).

- Concentration EQT VI/BSN Medical

Communication 2012/C 210/09, of the European Commission, published in the Official Journal of the European Union of 17 July 2012 - Prior notification of a concentration (Case COMP/M.6560 — EQT VI/BSN Medical).

- Antimicrobial Resistance

Council conclusions (2012/C 211/02) of 22 June 2012, published in the Official Journal of the European Union of 18 July 2012 – Conclusions on the impact of antimicrobial resistance in the human health sector and in the veterinary sector — a 'One Health' perspective.

- Concentration Tereos/Wilmar/JV

Communication 2012/C 215/03, of the European Commission, published in the Official Journal of the European Union of 21 July 2012 - Non-opposition to a notified concentration (Case COMP/M.6608 — Tereos/Wilmar/JV).

- Marketing Authorizations (EU) - June

Communication 2012/C 224/01, of the European Commission, published in the Official Journal of the European Union of 27 July 2012 - Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 June 2012 to 30 June 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 224/02, of the European Commission, published in the Official Journal of the European Union of 27 July 2012 - Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 June 2012 to 30 June 2012*(Decisions taken pursuant to Article 34 of Directive 2001/83/EC or Article 38 of Directive 2001/82/EC).*

- Concentration Sanofi-Aventis/Genzyme

Communication 2012/C 226/03, of the European Commission, published in the Official Journal of the European Union of 28 July 2012 - Non-opposition to a notified concentration (Case COMP/M.5999 — Sanofi-Aventis/Genzyme).

- Concentration Procter & Gamble/Arbora

Communication 2012/C 226/11, of the European Commission, published in the Official Journal of the European Union of 28 July 2012 - Prior notification of a concentration (Case COMP/M.6678 — Procter & Gamble/Arbora) — Candidate case for simplified procedure.

- Cross-border Living Organ Donations

Recommendation No S1 (2012/C 240/04) of 15 March 2012, published in the Official Journal of the European Union of 10 August 2012 – Refers to the financial aspects of cross-border living organ donations and recommends that (i) the competent authorities of an organ recipient should consider the access of the living donor to the health care system for problems related to the procedure of donation, (ii) the competent authorities of an organ recipient shall find a humanitarian solution and reimburse the benefits in kind necessitated by cross-border living donation for the donor, if the legislation covering the donor does not provide entitlement to sickness benefits in kind for the donor and (iii) the competent authority of the donor shall provide sickness cash benefits in accordance with the legislation it applies, regardless of which Member State the organ donation took place in or of who was the organ recipient.

- Concentration Solvay/Air Liquide/JV

Communication 2012/C 242/05, of the European Commission, published in the Official Journal of the European Union of 11 August 2012 - Non-opposition to a notified concentration (Case COMP/M.6511 — Solvay/Air Liquide/JV).

- Concentration Arla/Milk Link

Communication 2012/C 247/05, of the European Commission, published in the Official Journal of the European Union of 17 August 2012 - Prior notification of a concentration (Case COMP/M.6611 — Arla/Milk Link).

- Concentration Cytec Industries/Umeco

Communication 2012/C 252/01, of the European Commission, published in the Official Journal of the European Union of 22 August 2012 - Non-opposition to a notified concentration (Case COMP/M.6561 — Cytec Industries/Umeco).

- Concentration Bridgepoint/Orlando/Limoni

Communication 2012/C 252/05, of the European Commission, published in the Official Journal of the European Union of 22 August 2012 - Prior notification of a concentration (Case COMP/M.6670 — Bridgepoint/Orlando/Limoni) — Candidate case for simplified procedure.

- Active Implantable Medical Devices

Communication 2012/C 262/01, of the European Commission, published in the Official Journal of the European Union of 30 August 2012 - Commission communication in the framework of the implementation of the Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices *(Publication of titles and references of harmonised standards under the directive).*

- Medical Devices

Communication 2012/C 262/02, of the European Commission, published in the Official Journal of the European Union of 30 August 2012 - Commission communication in the framework of the implementation of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices *(Publication of titles and references of harmonised standards under the directive).*

- Medical Devices *in vitro*

Communication 2012/C 262/03, of the European Commission, published in the Official Journal of the European Union of 30 August 2012 - Commission communication in the framework of the implementation of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices *(Publication of titles and references of harmonised standards under the directive).*

- Marketing Authorizations (EU) - July

Communication 2012/C 264/01, of the European Commission, published in the Official Journal of the European Union of 31 August 2012 - Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 July 2012 to 31 July 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 264/02, of the European Commission, published in the Official Journal of the European Union of 31 August 2012 - Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 July 2012 to 31 July 2012*(Decisions taken pursuant to Article 34 of Directive 2001/83/EC or Article 38 of Directive 2001/82/EC).*

VI. EUROPEAN CASE-LAW

- Marketing Authorization

Case T-12/12, published in the Official Journal of the European Union of 11 August 2012 (2012/C 243/35): Judgment of the General Court of (Fifth Chamber) of 4 July 2012 — Laboratoires CTRS v Commission

I. Application for a declaration that the Commission failed to act in unlawfully failing to adopt a final decision in relation to the applicant's application for a marketing authorisation for the medicinal product Orphacol, and, in the alternative, for annulment of the decision, allegedly contained in the Commission's letter of 5 December 2011, not to grant that authorisation to the applicant.

II. Dismisses the application for a declaration of failure to act as inadmissible;

III. Rules that there is no longer any need to adjudicate on the application for annulment submitted in the alternative;

IV. Orders the European Commission to bear its own costs and to pay those incurred by Laboratoires CTRS;

V. *Orders the Czech Republic, the French Republic and the United Kingdom of Great Britain and Northern Ireland to bear their own respective costs.*

Licensing Scheme for the Operation of Pharmacies

Case C-84/11, published in the Official Journal of the European Union of 18 August 2012 (2012/C 250/09): Judgment of the Court (Third Chamber) of 21 June 2012 (reference for a preliminary ruling from the Korkein hallinto-oikeus — Finland)

I. Reference for a preliminary ruling — Korkein hallinto-oikeus — Interpretation of Articles 49 and 106(2) TFEU — Freedom of establishment — Licensing scheme for the operation of pharmacies — National law providing for a licensing scheme for the operation of pharmacies with conditions which are more favourable for University pharmacies than for private pharmacies — University Pharmacy having specific responsibilities relating to pharmacy teaching and to the supply of medicines.

II. *Article 49 TFEU must be interpreted as meaning that it does not preclude a national law, such as that at issue in the main proceedings, which provides for a licensing scheme for the operation of branch pharmacies specific to the Helsingin yliopiston apteekki which is more favourable than that applicable to private pharmacies, provided that — which is for the referring court to verify — the branches of the Helsingin yliopiston apteekki actually participate in the accomplishment of the specific tasks relating to the teaching of pharmacy students, research on pharmaceutical services and the manufacture of rare pharmaceutical preparations conferred on the latter by national law.*

Wholesale Distribution of Medicinal Products

Case C-7/11, published in the Official Journal of the European Union of 25 August 2012 (2012/C 258/07): Judgment of the Court (Second Chamber) of 28 June 2012 (reference for a preliminary ruling from the Tribunale di Palermo — Italy)

I. Reference for a preliminary ruling — Tribunale di Palermo –Interpretation of recital 36 and Articles 76 to 84 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67) — Wholesale distribution of medicinal products — Conditions under which authorisation may be granted for the wholesale distribution of medicinal products — National legislation which makes the wholesale distribution of medicinal products by pharmacists and persons authorised or entitled to supply medicinal products to the public subject to the requirement to obtain an authorisation imposed on wholesale distributors — Whether permissible.

II. Article 77(2) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, as amended by Commission Directive 2009/120/EC of 14 September 2009, must be interpreted as meaning that the requirement to obtain authorisation for the wholesale distribution of medicinal products is applicable to a pharmacist who, as a natural person, is also authorised under domestic law to operate as a wholesaler in medicinal products.

III. A pharmacist who is also authorised under domestic law to operate as a wholesaler in medicinal products must satisfy all the requirements imposed on applicants for and holders of authorisation for the wholesale distribution of medicinal products in Articles 79 to 82 of the Directive.

IV. *That interpretation cannot, of itself and independently of a law adopted by a Member State, give rise to or aggravate liability in criminal law on the part of a pharmacist who has engaged in activity as a wholesale distributor in medicinal products without the requisite authorisation.*



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