Revised Guidelines Good Distribution Practices Medicinal Products

On 15 July, 2011, the European Commission Directorate General for Health and Consumers (DG SANGO), published the draft of the revised Guideline on Good Distribution Practices of Medicinal Products for Human Use for public consultation.

The draft submitted to public consultation until 31 December, 2011, updates the former guidelines of 1994. The new guideline was prepared by the European Medicines Agency through its GMP/GDP Inspectors Working Group.

The guideline was revised to take into account the recent developments in the storage and distribution of medicinal products in the European Union and to meet new requirements for wholesale distributors and brokers established in the new Directive 2011/62/EU on falsified medicines.

Directive 2011/62/EU (amending Directive 2001/83/EC on the Comunity Code relating to medicinal products for human use) established measures to prevent the entry into the legal supply chain of falsified medicinal products.

It is recognized that the supply chain became more complex, namely by recognizing the quality of the *broker*.

Brokering of medicinal products, as defined in the said Directive, covers "all activities in relation to the sale or purchase of medicinal products, except for the wholesale distribution that do not include physical handling, and that consists of negotiating independently and on behalf of another legal or natural person."

The draft guideline is of particular interest to wholesale distributors and brokers of medicinal products for human use, as well as, for manufacturers who distribute their own products.

I. NATIONAL LEGISLATION

National Card of Blood Donor

Ministerial Order 255/2011, dated 1 July, published in the Official Gazette, 1rst Series, number 25, of 1 July 2011 – Approves the new national card of blood donor.

Electronic Prescription of Therapeutic and Diagnosis Complementary Means

Ministerial Dispatch 9186/2011, dated 21 July, published in the Official Gazette, 2 Series, number 139, of 21 July 2011 – Establishes that, as from 1 September 2011, the prescription of therapeutic and diagnosis complementary means shall be processed through electronic means.

Acquisition of Health Services – Lisbon and Tagus Valley Region

Resolution of the Council of Ministers 31/2011, published in the Official Gazette, 1 Series, number 146, 1 August, 2011 - Delegates powers to the Health Minister to authorize the acquisition of health services with a view of increasing the capacity to satisfy the needs of the beneficiaries of the Portuguese National Health Service ("NHS") in the Lisbon and Tagus Valley Region, as well as, the powers for the procedure and selection of the services provider.

Public Tender to manage the NHS customer service

Resolution of the Council of Ministers 37/2011, published in the Official Gazette, 1 Series, number 166, 30 August, 2011 – Authorizes the public tender to select the managing entity of the Customer Service of the NHS and the prorogation of the present contract until the conclusion of the new procedure, delegating to the Health Minister the powers to carry out the necessary acts.

II. EUROPEAN LEGISLATION

Measures to prevent the entry into the legal supply chain of falsified medicinal products

Directive 2011/62/EU, of the European Parliament and of the Council of 8 June 2011, published in the Official Journal of the European Union of 1 July of 2011 – Amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, to prevent the entry into the legal supply chain of falsified medicinal products.

Relevant modifications are introduced regarding the introduction of safety features in the medicinal products, common logos to be displayed on websites offering medicinal products for sale – implying several modifications regarding manufacturing authorizations and inspections to manufacturers and distributors. Each Member State shall transpose those measures into national law and apply those measures, as from 2 January 2013.

Food Information to Consumers

Information 2011/C 236 E/47 of the European Parliament published in the Official Journal of the European Union of 12 August of 2011 - Food information to consumers. European Parliament legislative resolution of 16 June 2010 on the proposal for a regulation of the European Parliament and of the Council on the provision of food information to consumers. Position of the European Parliament adopted at first reading on 16 June 2010 with a view to the adoption of a Regulation of the European Parliament and of the Council on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directives 94/54/EC and 1999/10/EC, Directive 2000/13/EC, Commission Directives 2002/67/EC and 2004/77/EC and Commission Regulation (EC) No 608/2004.

Medical Devices

Communications 2011/C 242/01, 2011/C 242/02 and 2011/C 242/03 of the European Commission, published in the Official Journal of the European Union of 19 August of 2011 - Publication of titles and references of harmonised standards under the directives (i) 90/385/EEC of 20 June 1990 on active implantable medical devices, (ii) 93/42/EEC of 14 June 1993 concerning medical devices and (iii) 98/79/EC of the of 27 October 1998 on in vitro diagnostic medical devices.

Food – Official Control of levels

Commission Regulation (EU) No 836/2011 of 19 August 2011 published in the Official Journal of the European Union of 20 August of 2011 – Amends Regulation (EC) No 333/2007 laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs.

Marketing Authorizations granted/modified by EMA from 1 May to 30 June 2011

Informations 2011/C 250/01 and 2011/C 250/02, published in the Official Journal of the European Union of 26 August of 2011 - Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 May 2011 to 30 June 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.

III. INFARMED – NEWS

Shortage – medicinal products in pharmacies

Information Note 126/CD, 7 July 2011 – Warns the holders of marketing authorizations, distributors and pharmacies to comply with their legal duties ensuring the adequate management of the quantities of products and abstaining to carry out acts that are not included within the range of the respective authorizations, otherwise such infraction will be sanctioned as established in Decree-Law 176/2006, of 30 August.

Protocol against the risks of counter faction of medicinal products

Protocol against the risks of counter faction of medicinal products - With the aim of fighting against counter faction and to ensure the quality in the medicinal products chain, INFARMED, APIFARMA, and VALORMED and the Customs and Special Taxes General Directorate signed on 16 July 2011, a collaboration protocol. Pursuant to this document the medicines and health products sent by post or by express cargo that have been counterfeit or that are not in conformity, shall be apprehended and destroyed, as they constitute a risk to public health.

Rectification – Homogeneous groups 3 Q 2011

Information Note 137/CD, 21 July 2011 – Rectification of the homogeneous groups for the 3Q 2011 – regards the medicinal products that are included in the group GH0382.

Expiry of State Pricing Reimbursements (July 2011)

Resolution of the Board of INFARMED, 21 July 2011- Publishes the definitive list of the medicinal products regarding which was decided the respective expiry as a result of not being commercialized in July 2011.

Imports of Medicinal Products for Personal Use

Information Note 148/CD, 29 July 2011 – It is not permitted to import medicinal products for personal use. In case of need to use a medicinal product that is not

authorized/available in Portugal, it should be obtained pursuant to an authorization for special use, which may only be requested by pharmacies/hospitals.

- **Expiry of State Pricing Reimbursements (August 2011)**

Resolution of the Board of INFARMED, dated 17 August 2011 - Publishes the definitive list of the medicinal products regarding which was decided the respective state reimbursement, as a result of not having been commercialized in August 2011.

IV. ACSS – NHS Centralised Purchases Authority

- **Electronic Prescription**

Information Notes 24 and 27, of 1 July 2011 and 5 July 2011- Electronic Prescription.

- **Costs with Medicinal Products**

Information Note 25, of 4 July 2011 – Related with the accounting registration of the costs with medicinal products, confirmed by the State Invoicing Confirmation Centre.

- **Moderating Fees**

Information Note 26, 5 July 2011 – Clarifies that the period to recover moderating fees due to the NHS is of 3 years.

- **Reduction of costs with the transportation of patients**

Regulation 17, 21 July 2011 - Establishes the reduction of the costs with the non urgent transportation of patients to 1/3 comparing with the 2010 costs, pursuant to paragraph 3.83 of the Troika MOU.

- **External Audits - NHS**

Regulation 20, 26 July 2011 - Establishes external audits to clinical codification by the institutions of the NHS.

- **Suspension of direct payments to the beneficiaries of the NHS**

Regulation 22, 9 August 2011- Establishes the immediate and mandatory suspension in all institutions and services of the NHS of the direct payments to patients.

- **Leave without Pay**

Information Note 29, 22 August 2011 – As from 9 August 2011 it is no longer legally admissible to grant leaves without pay in the NHS, pursuant to articles 21 and 22 of the Statute of the NHS, approved by Decree-Law 11/93, 15 January 1993.

V. ASST – Blood and Transplantation Authority

- **Activites report regarding 2011**

Contains the facts sheet regarding the activity of collection of organs and transplantation in the 1srt semester 2011

VI. COMUNICATIONS – European Documents

- **Concentration Pfizer/Ferrosan**

Communication 2011/C 191/03, of the European Commission, published in the Official Journal of the European Union of 1 July 2011 - Non-opposition to a notified concentration (Case COMP/M.6162 — Pfizer/Ferrosan Consumer Healthcare Business).

- **Childhood immunisation**

Council Conclusions 2011/C 202/02, published in the Official Journal of the European Union of 8 July 2011 - Childhood immunisation: successes and challenges of European childhood immunisation and the way forward.

- **Medical Devices**

Council Conclusions 2001/C 202/03 published in the Official Journal of the European Union of 8 July 2011 - Innovations on the medical devices sector.

- **Concentration Eli Lilly/Janssen animal**

Communication 2011/C 235/01, of the European Commission, published in the Official Journal of the European Union of 11 August 2011 - Non-opposition to a notified concentration (Case COMP/M. M.6205 — Eli Lilly/Janssen Pharmaceutica animal health business assets).

- **Concentration Takeda/Nycomed**

Communication 2011/C 240/02, of the European Commission, published in the Official Journal of the European Union of 18 August 2011 - Non-opposition to a notified concentration (Case COMP/M. M.6278-Takeda/Nycomed).

- **Data protection in the European Union**

Opinion 2011/C 248/21 of the European Economic and Social Committee, published in the Official Journal of the European Union of 25 August 011- Opinion on the Communication from the Commission to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions — A comprehensive approach on personal data protection in the European Union.

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