New Rules regarding the Prescription and Dispensing of Medicinal Products

On May 11, was published Ministerial Order No 137-A/2012, establishing the legal framework for the prescription of medicinal products ruling the conditions of dispensing the cheapest medicinal product, as well as the duties to inform the patients of their option rights, all in compliance with Law No 11/2012 of 8 March, (Law of the Prescription by INN).

A new context has been defined revising substantially the rules applicable to the medical prescriptions and sales of medicinal products, changing the market of the sales to out-patients.

The new rules apply to all medicinal products for human use subject to medical prescription, including manipulated medicinal products and medicinal products containing narcotics or psychotropic substances, whichever is the place of the prescription. It also applies to the prescription of other reimbursed products by the State and its pricing, in particular products for self management of diabetes *mellitus* and dietetic products.

The Infarmed (the Portuguese Agency) and ACSS (Public entity centralizing public purchases) published a Joint Informative Note (Joint Informative Note No 01/INFARMED/ACSS), establishing specific guidelines addressed to the prescribers, the pharmacies and the companies developing informatic systems.

Concerning the information to the prescribers:

(i) the prescription must be written by INN (International Nonproprietary Name), pharmaceutical form, dosage, presentation and posology;

(ii) until the publication of the rules and adaptation of the informatic system, all the prescriptions with the brand name of a medicinal product, without including the technical justification, are considered to be made to the INN and the pharmacy must dispense the cheapest medicinal product to the patient, except if the patient chooses otherwise;

(iii) the prescription including the brand name is only allowed with respect to medicinal products which (i) do not have reimbursed generics (ii) or for which the original branded medicinal product and licenses are unique and in the admissible exceptions, including the respective technical justification of the physician within the prescribed medicinal product in certain situations, and

(iv) the hand written prescription is only allowed in exceptional situations and the word "Exception" must be inserted under the logo of the Ministry of Health.

In relation to the pharmacies, the pharmacists shall inform the patients of the cheapest medicinal products on the market, that comply with the medical prescription, and must maintain a stock of, at least 3 medicinal products of each homogeneous group, chosen among the five medicinal products with lower price in the market and, must sell the cheapest one to the patient.
The cost of the 'fifth lower price' is registered in a database provided daily by the Infarmed to the companies of the sector.
When dispensing, the pharmacist must inform the patient of the availability of a cheaper medicinal product, reimbursed by the NHS, available in the pharmacy that complies with the medical prescription. The patient must be informed of the right to opt for the medicinal product which is in compliance with the medical prescription and of the right to the cheapest medicinal product in the market, which must be available within 12 hours, with no additional costs, in case it is not available at the pharmacy.
Moreover, the above mentioned Informative Note establishes rules applicable in three different situations (i) prescription by INN (or absence of the exceptions) when there is a homogeneous group, (ii) prescription by INN (or absence of the exceptions) when there is no homogeneous group and (iii) prescription by brand when the treatment exceeds 28 days.

Concerning the information to the patients, the patients may request information to the doctor or to the pharmacist regarding the price of the medicinal products and regarding the situations they can choose, as well as to aceed to that information on Infarmed's *website*. Whenever the patient is entitled to opt, the patient at stake must write the sentence "right to opt" on the back side of the prescription and sign.

To complement these guidelines, the Infarmed made available on its *website* FAQ's concerning the rules on prescription and dispensing of medicinal products, only to be applied during the transitory period of the Ministerial Order (until 1 September 2012).

The Ministerial Order came into force on 1 June 2012 and establishes a transitory period of 90 days (until 1 September 2012) for the publication of the technical rules regarding the prescription, dispensing, conference and identification of the prescriber and of the patients and setting a further 90 days period for the adaptation of the electronic systems required to implement the new prescription and dispensing rules.

I. NATIONAL LEGISLATION

NHS and Patients Transportation

Ministerial Order No 142-A/2012, published in the Official Gazette, 1 Series, Number 94, of 15 May 2012 – Third amendment to the Ministerial Order No 1147/2001 of 28 September, which approves the Regulation of Patients Transport, determining that non-urgent patient transportations can be performed by ambulances and light-duty vehicles of simple transportation.

Ministerial Order No 142-B/2012, published in the Official Gazette, 1 Series, Number 94, of 15 May 2012 – Defines the conditions according to which the National Health Service (NHS) supports the costs with non-urgent patient transportation which is instrumental for the providence of health benefits.

Payment of Acts of Health Authorities and other Services

Decree-Law No 106/2012, published in the Official Gazette, 1 Series, Number 96, of 17 May 2012 – Proceeds to the first amendment of Decree-Law No 8/2011 of 11 January, which approves the amounts due regarding acts of the health authorities and services provided by other public health professionals.

Approval of Statutes

Ministerial Order No 153/2012, published in the Official Gazette, 1 Series, Number 99, of 22 May 2012 – Approves the Statutes of the Regional Health Administration of the North (Administração Regional de Saúde do Norte, I.P.) and revokes Ministerial Order No 649/2007 of 30 May.

Ministerial Order No 155/2012, published in the Official Gazette, 1 Series, Number 99, of 22 May 2012 – Approves the Statutes of the Central Administration of the Health System (Administração Central do Sistema de Saúde, I.P.).

Ministerial Order No 156/2012, published in the Official Gazette, 1 Series, Number 99, of 22 May 2012 – Approves the Statutes of the Regional Health Administration of the Algarve (Administração Regional de Saúde do Algarve, I.P.) and revokes Ministerial Order No 653/2007 of 30 May.

Ministerial Order No 157/2012, published in the Official Gazette, 1 Series, Number 99, of 22 May 2012 – Approves the Statutes of the Regional Health Administration of Alentejo (Administração Regional de Saúde do Alentejo, I.P.) and revokes Ministerial Order No 652/2007 of 30 May.

Ministerial Order No 158/2012, published in the Official Gazette, 1 Series, Number 99, of 22 May 2012 – Approves the Statutes of the National Institute of Medical Emergency (Instituto Nacional de Emergência Médica, I.P.) and revokes Ministerial Order No 647/2007 of 30 May.

Ministerial Order No 161/2012, published in the Official Gazette, 1 Series, Number 99, of 22 May 2012 – Approves the Statutes of the Regional Health Administration of Lisboa and Vale do Tejo (Administração Regional de Saúde de Lisboa e Vale do Tejo, I.P.) and revokes Ministerial Order No 651/2007 of 30 May.

Ministerial Order No 162/2012, published in the Official Gazette, 1 Series, Number 99, of 22 May 2012 – Approves the Statutes of the National Health Institute Doutor Ricardo Jorge (Instituto Nacional de Saúde Doutor Ricardo Jorge) and revokes Ministerial Order No 812/2007 of 27 July.

Ministerial Order No 164/2012, published in the Official Gazette, 1 Series, Number 99, of 22 May 2012 – Approves the Statutes of the Regional Health Administration of the Centre (Administração Regional de Saúde do Centro, I.P.) and revokes Ministerial Order No 650/2007 of 30 May.

Ministerial Order No 165/2012, published in the Official Gazette, 1 Series, Number 99, of 22 May 2012 – Approves the Statutes of the Portuguese Institute of Blood and Transplantation (Instituto Português do Sangue e da Transplantação, I.P.), and revokes Ministerial Order No 811/2007 of 27 July.

Nuclear Structure

Ministerial Order No 154/2012, published in the Official Gazette, 1 Series, Number 99, of 22 May 2012 – Sets the nuclear structure of the Service of Intervention in Addictive Behaviours and Addictions (Serviço de Intervenção nos Comportamentos Aditivos e nas Dependências).

Ministerial Order No 159/2012, published in the Official Gazette, 1 Series, Number 99, of 22 May 2012 – Sets the nuclear structure of the Directorate-General for Health (Direcção-Geral da Saúde).

Ministerial Order No 160/2012, published in the Official Gazette, 1 Series, Number 99, of 22 May 2012 –Sets the nuclear structure of the

Secretariat-general of the Ministry of Health (Secretaria-Geral do Ministério da Saúde).

- Liabilities Law

Decree-Law No 127/2012, published in the Official Gazette, 1 Series, Number 119, of 21 June 2012 – Sets forth the legal provisions which regulate the necessary proceedings for the application of the Liabilities and Late Payments Law, approved by Law No 8/2012, of 21 February and the implementation of the disclosure of information, therein established.

- Patient Moderating Fees Regime

Decree-Law No 128/2012, published in the Official Gazette, 1 Series, Number 119, of 21 June 2012 – Proceeds to the first amendment of Decree-Law No 113/2011, of 29 November, which regulates de access to the social benefits of the NHS by the beneficiaries of the NHS in what concerns the patient moderating fees regime and to the application of special benefits regimes.
The conditions for the exemption of fees in case of involuntary unemployment are revised, amendments to the regime of patient transportation are made; The infringements regime is integrated in Decree-Law Nº 113/2011, so that the process to recover moderating fees due by the patients is more agile and effective through a centralized management of proceedings.

II. LEGISLATION OF THE EUROPEAN UNION

- Health Food

Regulation (EU) No 378/2012 of the European Commission, published in the Official Journal of the European Union of 4 May 2012 - Refuses to authorise certain health claims made on foods and referring to the reduction of disease risk and to children's development and health.

Commission Regulation (EU) No 432/2012, published in the Official Journal of the European Union of 25 May 2012 - Establishes a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health.

- Pharmacovigilance

Commission Implementing Regulation (EU) No 520/2012, published in the Official Journal of the European Union of 20 June 2012 – Concerns the performance of pharmacovigilance activities provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council.

III. INFARMED

- Amendments to the System of Notification of Stock-outs

Information Note No 112/CD of 22 May 2012 – Deliberation No 50/CD/2012 of 12/04/2012 was published, with the purpose of improving the information provided regarding the stock-out situations, to all those operating on the health sector, specially to health professionals; Entered into force on 12 May 2012 being applicable to all medicinal products (OTC or subject to medical prescription) and complements the current way of notification of the stock-outs or of the termination of commercialization.

- Medicinal Products with a Narrow Therapeutic Index or Margin

Information Note No 114/CD of 22 May 2012 – The Infarmed has defined the active substances with a narrow therapeutic index or margin, which are contained in the list of the annex of Deliberation No 070/CD/2012 of 24/05/2012 (with consequences regarding the obligations in case of stock-outs).

- 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 May 2012.

- Rules on Prescription and Dispensing of Medicinal Products – Transitory Rules

Joint Information Note No 01/INFARMED/ACSS of 24 May 2012 – The rules on prescription and dispensing of medicinal products were recently amended through the publication of Law No 11/2012 of 8 March and the Ministerial Order No 137-A/2012 of 11 May. The Ministerial Order entered into force on 1 June and establishes a transitory period of 90 days for the publication of the mentioned rules and another 90 days for the adaptation of the electronic systems. In this Information Note, Infarmed and ACSS provide for specific guidelines to the prescribers, the pharmacies and to the companies which develop the informatics systems.

- Collection and Donation of Medicinal Products

Information Note No 133/CD of 6 June 2012 – Infarmed alerts that the collection and donation of medicinal products previously dispensed and its subsequent redistribution cannot be carried out once the storage conditions are no longer guaranteed, pursuant to the Good Distribution Practices of Medicinal Products. Whenever the medicinal product is dispensed to the general public, the adequate conditions are no longer guaranteed, and, consequently, the pharmacist

can no longer assure the quality of the medicinal product.
The Infarmed reaffirms that all the medicinal products that have been dispensed to the general public cannot be collected for subsequent donation.

- Option Right of the Patient

Information Note No 141/CD of 22 June 2012 – Infarmed clarifies doubts presented by some beneficiaries of the NHS and pharmacies regarding the option right, established in article 13 of the Ministerial Order No 137-A/2012, of 11 May, namely that, whenever the patient chooses a medicinal product, his/her signature must be included on the back side of the medical prescription – confirming the medicinal products that were dispensed to him/her, and the sentence "Option Right" – handwritten or pre-printed – confirming that he/she has exercised the option right. The patient must sign the medical prescription thereby confirming that the medicinal products were dispensed to him/her, and, in the case of wanting to exercise the option right, sign again after the sentence "Option Right".

- Notification of Incidents with Medical Devices – Legal Requirement

Information Note No 144/CD/9.1.4. of 26 June 2012 – The European Commissioner for Health and Consumers Policy, John Dalli, requested the Member States to adopt immediate measures regarding the strict implementation of the current medical devices legislation, after the PIP breast implants case.
Therefore, Infarmed recalls that the notification of incidents with medical devices by health professionals is a requirement which allows the risk management and guarantees better security levels within the use of medical devices.

- Sale of Veterinary Medicinal Products

Information Note No 151/CD/8.1.6. of 28 June 2012 – The dispensing of medicinal products for animal health requires the compliance with legal provisions to guarantee the adequate care of the animal and food health of the consumers. The Infarmed sets certain requirements to be complied with, concerning the dispensing of medicinal products, veterinary medicinal products subject to veterinary medical prescription and veterinary medicinal products extemporaneously prepared.

IV. ACSS - NHS Centralised Purchases Authority

- Non-urgent Transport of Patients

Information Note No 13 of 1 June 2012 – Non-urgent transport of patients – Legal Framework, Access, types of transportation and charges. This information note refers to the approval of the General Regulation regarding the Access of Patients to the non-urgent transport.

Regulation No 26 of 3 May 2012 – Sets the rules regarding the reduction of costs and costs bearing regarding the non-urgent transport of patients.

- Patient Moderating Fees

Information Note No 14 of 26 June 2012 – Infringement procedures regarding the use of the health services without payment of moderating fees. The ACSS is the competent authority to start the procedures; therefore, it is already developing, jointly with SPMS, a group of standard procedures to allow to dematerialized communications of the records of the evidence and debt certificates to the Tax and Customs Authority.

Regulation No 30 of 21 May 2012 – means of evidence of the exemption by patients regarding moderating fees – Unemployed patients.

- Liabilities Law

Regulation No 28 of 21 May 2012 – Implementation of the Liabilities and Late Payments Law.

V. COMUNICATIONS – European Documents

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

Communication 2012/C 135/02, of the European Commission, published in the Official Journal of the European Union of 9 May 2012 - Non-opposition to a notified concentration (Case COMP/M.6438 — Saria/Teeuwissen/Jagero II/Quintet/Bioiberica).

- Concentration Limagrain/KWS/Genective JV

Communication 2012/C 135/10, of the European Commission, published in the Official Journal of the European Union of 9 May 2012 - Prior notification of a concentration (Case COMP/M.6454 — Limagrain/KWS/Genective JV) — Candidate case for simplified procedure.

- Concentration Solvay/Air Liquide/JV

Communication 2012/C 136/07, of the European Commission, published in the Official Journal of the European Union of 11 May 2012 - Prior notification of a concentration (Case COMP/M.6511 — Solvay/Air Liquide/JV) — Candidate case for simplified procedure.

- Food Health

Communication 2012/C 136 E/02, of the European Commission, published in the Official Journal of the European Union of 11 May 2012 – Approval of the text concerning the recognition of agriculture as a strategic sector in the context of food security, following the European Parliament resolution of 18 January 2011 on recognition of agriculture as a strategic sector in the context of food security.

- Alzheimer Disease

Communication 2012/C 136 E/07, of the European Commission, published in the Official Journal of the European Union of 11 May 2012 – Approval of the text concerning the European initiative on Alzheimer's disease and other dementias, following the European Parliament resolution of 19 January 2011 on a European initiative on Alzheimer's disease and other dementias.

- Health for Growth Programme

Communication 2012/C 143/19, of the European Commission, published in the Official Journal of the European Union of 22 May 2012 – Opinion of the European Economic and Social Committee on the 'Proposal for a Regulation of the European Parliament and of the Council on establishing a Health for Growth Programme, the third multiannual programme of EU action in the field of health for the period 2014-20'.

- Information regarding Medicinal Products

Communication 2012/C 143/30, of the European Commission, published in the Official Journal of the European Union of 22 May 2012 – Opinion of the European Economic and Social Committee on the 'Amended proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 726/2004 as regards information to the general public on medicinal products for human use subject to medical prescription and as regards pharmacovigilance'.

Communication 2012/C 143/31, of the European Commission, published in the Official Journal of the European Union of 22 May 2012 – Opinion of the European Economic and Social Committee on the '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 medicinal prescription and as regards pharmacovigilance'.

- Concentration Posco/MC/MCHC/JV

Communication 2012/C 144/08, of the European Commission, published in the Official Journal of the European Union of 23 May 2012 – Prior notification of a concentration (Case COMP/M.6555 — Posco/MC/MCHC/JV) — Candidate case for simplified procedure.

- Marketing Authorizations

Communication 2012/C 148/01, of the European Commission, published in the Official Journal of the European Union of 25 May 2012 – Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 April 2012 to 30 April 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 148/02, of the European Commission, published in the Official Journal of the European Union of 25 May 2012 – Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 April 2012 to 30 April 2012*(Decisions taken pursuant to Article 34 of Directive 2001/83/EC or Article 38 of Directive 2001/82/EC).*

- Concentration Procter & Gamble/TEVA OTC Business

Communication 2012/C 171/01, of the European Commission, published in the Official Journal of the European Union of 16 June 2012 – Non-opposition to a notified concentration (Case COMP/M.6280 — Procter & Gamble/TEVA OTC Business).

- Concentration Princes/ARIA

Communication 2012/C 182/01, of the European Commission, published in the Official Journal of the European Union of 22 June 2012 – Non-opposition to a notified concentration (Case COMP/M.6249 — Princes/ARIA).

- Marketing Authorizations

Communication 2012/C 190/01, of the European Commission, published in the Official Journal of the European Union of 29 June 2012 – Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 May 2012 to 31 May 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 190/02, of the European Commission, published in the Official Journal of the European Union of 29 June 2012 – Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 May 2012 to 31 May 2012*(Decisions taken pursuant to Article 34 of Directive 2001/83/EC or Article 38 of Directive 2001/82/EC).*

VI. EUROPEAN CASE-LAW

Supplementary Protection Certificate

Case C-574/11, published in the Official Journal of the European Union of 5 May 2012: Order of the Court (Eighth Chamber) of 9 February 2012 (reference for a preliminary ruling from the Landgericht Düsseldorf — Germany) — Novartis AG v Actavis Deutschland GmbH & Co KG, Actavis Ltd

I. Reference for a preliminary ruling — Landgericht Düsseldorf — Interpretation of Articles 4 and 5 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) — Scope of the certificate — Protection solely of medicinal products consisting only of the protected active ingredient or protection extended to medicinal products consisting of the protected active ingredient in combination with another active ingredient;

II. *Articles 4 and 5 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 meaning that, where a 'product' consisting of an active ingredient was protected by a basic patent and the holder of that patent was able to rely on the protection conferred by that patent for that 'product' in order to oppose the marketing of a medicinal product containing that active ingredient in combination with one or more other active ingredients, a supplementary protection certificate granted for that 'product' enables its holder, after the basic patent has expired, to oppose the marketing by a third party of a medicinal product containing that product for a use of the 'product', as a medicinal product, which was authorised before that certificate expired.*

Placement of Medicinal Products in the Market at a Lower Price

Case C-185/10, published in the Official Journal of the European Union of 26 May 2012: Judgment of the Court (Third Chamber) of 29 March 2012 — European Commission v Republic of Poland

I. Failure of a Member State to fulfil obligations — Infringement of Article 6 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) — Legislation of a Member State permitting medicinal products having a lower price and characteristics similar to authorised products to be marketed in that State without prior authorisation;

II. Declares that, by adopting and maintaining in force Article 4 of the Law on Medicinal Products (Prawo farmaceutyczne) of 6 September 2001, as amended by the Law of 30 March 2007, inasmuch as that statutory provision dispenses with the requirement for a marketing authorisation for medicinal products from abroad which have the same active substances, the same dosage and the same form as those having obtained a marketing authorisation in Poland, on condition that, in particular, the price of those imported medicinal products is competitive in relation to the price of products having obtained such authorisation, the Republic of Poland has failed to fulfil its obligations under Article 6 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 Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007;

III. *Orders the Republic of Poland to pay the costs.*

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