Patients Moderating Fees of the National Health System

The principles and laws governing the national health system (NHS) are not empty words, once the right to healthcare has been one of the rights protected and guaranteed by the Portuguese State in the last 30 years – the existence of a universal and comprehensive NHS is currently a reality.

The right to healthcare is secured by the State through a universal and comprehensive NHS, for it includes all the population in general and guarantees the entire healthcare and medical assistance and not just part of it.

In addition, taking into consideration the social and economic conditions of the citizens, the NHS should be mostly free. It should be noted that the beneficiaries are not only the Portuguese citizens, irrespectively of the social security system they are subject to, but also citizens which are nationals from other Member States of the European Union, according to the applicable European Union law, and also foreign citizens residing in Portugal. This means that the universal, comprehensive and mostly free NHS comprehends anyone who is resident in Portugal.

In order to be able to grant the access to the population to a good healthcare, disregarding of the respective financial situation, the Portuguese State must guarantee a rational and efficient network of human resources and health units.

The major issue is the sustainability of the NHS, in other words, how can we maintain the NHS economically sustainable without compromising its universal and comprehensive nature?

According to the Memorandum of Understanding with the Troika, the sustainability of the NHS leads, among other measures, to the substantial revision of the current categories of exemptions, including a more strict application of the condition of economic insufficiency and the increase of the Patients Moderating Fees in certain services.
In line with the Memorandum, it should be secured that the Patients Moderating Fees for primary healthcare are lower than the fees applicable to specific medical care appointments and than those of the emergencies services, as well as, the automatic indexation of the Patients Moderating Fees of the NHS to the inflation.

On 29 November, this measure was implemented through the publication of a new legal framework for Patients Moderating Fees (Decree-Law 113/2011), which comes into force on 1 January 2012.

The Patients Moderating Fees are just a small part of the costs borne by the NHS for the healthcare services provided to the patients. All the procedures to be fulfilled by the NHS have a cost which is fixed in the prices list of the NHS, taking into consideration the respective direct and indirect real costs. Since the system is progressively free, as long as its universal and comprehensive nature is guaranteed, providing of healthcare may have a cost for the user which is equivalent to the Patients Moderating Fees. As the meaning of the designation of Moderating Fees indicates, the fees only represent part of the costs of the healthcare services, and can never be, in any case, higher than one third of their real cost.

The Patients Moderating Fees are due for the appointments of primary health care services provided at home, hospitals or in other private or public health units, namely entities with an agreement with the NHS. Patients Moderating Fees are also due in case of complementary diagnostic and therapeutic exams, except exams undertaken during the period of Hospital stays.
It should be noted that this legal framework is limited with exemptions and dispensations of payment of the Patients Moderating Fees.
The groups that are exempt are namely pregnant women and women giving birth, children up to 12 years old and patients with an incapacity level equal or higher than 60%.

The patients which are exempt for these reasons are approximately 2 million, according to the information provided by the Ministry of Health and disclosed to the Media.
The patients in a situation of financial insufficiency are also exempted, which includes those that belong to a family with an average monthly income equal or less than 628,83 Euros – this is 1, 5 the value of the social support index currently 419,22 Euros.

On the other hand, it is also established by law that patients with certain pathologies are also exempt including, serious diseases, as well as patients in need of respiratory care at home or dialysis.

According to the news released by the Media, 3 million of Portuguese which are not covered by the exemptions, must pay, each one, just 2.5 Euros more per month, meaning 30 Euros more per year. According to the estimates of the Ministry of Health, approximately 72% of the population in Portugal will be exempt.

Ministerial Order 311-D/2011, of 27 of December establishes the criteria of verification of the condition of financial insufficiency of patients for the purpose of the exemption of the Patients Moderating Fees and other costs incurred due to access to healthcare services within the NHS. It establishes the rules to assess the amount of the family's monthly income, the family composition, the number of family members and the means to produce evidence of the requirements that need to be met to obtain the exemption based on the financial insufficiency.

I. NATIONAL LEGISLATION

- Incentive to the Consumption of National Food

Resolution of the Parliament No 143/2011, published in the Official Gazette, 1 Series, number 211, of 3 November, 2011 – Recommends the Government to take measures to provide incentives to the consumption of national food.

- Inclusion of Pharmaceutical Products Associations of Bronchodilator and Anti-asthmatics Medicinal Products

Ministerial Order No 289-A/2011, published in the Official Gazette, 1 Series, number 211, of 3 November, 2011 – Maintains into force until the 1 December of 2011 the inclusion of the associations of bronchodilator and anti-asthmatics (5.1.) in level B, in the sequence of the Ministerial Order No 1263/2009, of 15th October and article 3 of the Ministerial Order No 924-A/2010, of 17 of September.

- Electronic Prescription of Medicinal Products

Dispatch No 15096/2011, published in the Official Gazette, 2 Series, number 214, of 8 November, 2011 – Determines, in the context of medicinal products electronic prescription, the update of the data related to the identification of the medical prescribers and dentists and odontologists, for the purpose of reimbursement and monitoring of the prescription.

- Shared Services of the Ministry of Health (SPMS) responsible for Integrated Systems of Health Information

Decree-Law No 108/2011, published in the Official Gazette, 1 Series, number 221, of 17 November, 2011 – Attributes to the Shared Services of the Ministry of Health (SPMS) powers within Information and Communication Technologies, acting in conformity with the restructuring of the Central Administration of the Health System I.P., being the SPMS responsible for the development, maintenance and operation of several integrated systems of health information.

- Pricing Legal Framework

Decree-Law No 112/2011, published in the Official Gazette, 1 Series, number 229, of 29 November, 2011 – Approves the pricing legal framework of reimbursed medicinal products subjected to medical prescription and not subjected to medical prescription, along with the following amendments (i) it is expected that the maximum public selling price of the first generic to be introduced in the market should be equal or inferior to 50% of the price of the reference product with the same active substance, safe certain exceptions (ii) revises the current system of prices revision, changing the countries of reference to Spain, Italy and Slovenia (iii) the marketing margins for wholesalers and pharmacies become regressive and (iv) a single point of reception of the marketing authorization requests, public selling price authorizations and reimbursement of medicinal products is established and managed by the Infarmed in articulation with the DGAE.

- Patients Moderating Fees and Special Benefits Regime

Decree-Law No 113/2011, published in the Official Gazette, 1 Series, number 229, of 29 November, 2011 – Rules the access of patients to the NHS in what concerns to the Patients Moderating Fees and the application of a special benefits regime.

- Disputes Arising from Industrial Property Rights

Law No 62/2011, published in the Official Gazette, 1 Series, number 236, of 12 December, 2011 – Creates a legal framework applicable to disputes emerging from industrial property rights, when the reference medicinal products and generic medicinal products are at stake, being from that moment onwards subjected to mandatory arbitration, institutionalized or not, in the case of patents of process, patents of product or use, or supplementary protection certificates, therefore amending for the fifth time the Decree-Law No 176/2006 of 30th August, and the proceeding for the amendment of the legal framework of the State reimbursements of the medicinal products price, approved and annexed to the Decree-Law No 48-A/2010 of 13 May. Establishes, as well, that the public selling price of generic medicinal products to be introduced in the market should be equal or less than 50% of the public selling price of the medicinal product of reference.

- Patients Financial Condition for the Exemption of Patients Moderating Fees

Ministerial Order No 311-D/2011, published in the Official Gazette, 1 Series, number 247, of 27 December, 2011 – Establishes the criteria for the verification of the condition of financial insufficiency of the patients for the purpose of obtaining the exemption from the Patients Moderating Fees and other costs incurred due to the access to healthcare services within the NHS, in the sequence of Decree-Law No 113/2011 of 29 November which revised the Patients Moderating Fees.

- Eradication of HIV/AIDS

Resolution of the Parliament No 161/2011, published in the Official Gazette, 1 Series, number 249, of 29 December, 2011 – Recommends the Government to adopt measures aimed at combating the HIV/AIDS infection in Portugal, therefore pursuing its eradication.

- Organic Law of the Ministry of Health

Decree-Law No 124/2011, published in the Official Gazette, 1 Series, number 249, of 29 December, 2011 – Approves the Organic Law of the Ministry of Health in the context of the Efficiency Commitment, reinforcing the powers of the Directorate-General of Health, of the General Inspection of the Health Activities and the

General Secretariat. The powers regarding the planning of human resources and the preparation of the budget of the Ministry oh Health is transferred to the Central Administration of the Health System, IP, and also a restructuring of the Portuguese Blood Institute, IP, is restructured, among other measures.

II. LEGISLATION OF THE EUROPEAN UNION

- Preventive Health Measures

Commission Delegated Regulation (EU) No 1152/2011 of 14 July 2011, published in the Official Journal of the European Union, of 15 November 2011 – Supplements Regulation (EC) No 998/2003 of the European Parliament and of the Council as regards preventive health measures for the control of *Echinococcus multilocularis* infection in dogs for non-commercial movements to the territories of Member States or part of it.

- Health in Food Matters

Commission Regulation (EU) No 1160/2011 of 14 November 2011, published in the Official Journal of the European Union, of 15 November 2011 – Concerns the authorization and refusal of authorization of certain health claims made on foods and referring to the reduction of disease risk, on the basis of the Regulation (EU) 1924/2006, of the European Parliament and the Council, of 20th December 2006, related to the health and nutritional claims made on foods, and establishes the health claims made on foods which are allowed within the European Union.

- Food Information

Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011, published in the Official Journal of the European Union, of 22 November, 2011 – Aims to guarantee a high level of consumer protection in what concerns the provision of food information to consumers and simultaneously secures a good functioning of the internal market, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004.

- Protection Measures regarding the Avian Influenza

Commission Implementing Decision of 14 December 2011, published in the Official Journal of the European Union, of 16 December 2011 – Amends Decision 2006/415/EC concerning certain protection measures in relation to highly pathogenic avian influenza of the subtype H5N1 in poultry in the Community *(notified under document C(2011) 9169)*.

- In-Vitro Diagnostic Medical Devices

Commission Directive 2011/100/EU of 20 December 2011, published in the Official Journal of the European Union, of 22 December 2011 – Amends Directive 98/79/EC of the European Parliament and of the Council on *in-vitro* diagnostic medical devices, namely its Annex II, regarding the tests to the variant of *Creuzfeldt-Jakob* (vDCJ).

III. INFARMED – NEWS

- Utilization of injectable gel based in Hyaluronic Acid in Breast Tissue

Information Note No 228/CD of 9 November 2011 – The Infarmed recommends a careful use in the utilization of injectable gel based in Hyaluronic Acid, once repeated injections in the breast tissue may cause the formation of encapsulated nodules which make the interpretation of the breast tissue X-ray more difficult.

- Suspension of the company Crossbridge Produtos Farmacêuticos Lda

Information Note No 225/CD of 4 November 2011 – Following the detection of irregularities, the Infarmed suspended the activity of medicinal products wholesale distribution of the company Crossbridge Produtos Farmacêuticos Lda.

- Medicinal Products Advertising on the website of Pharmaceutical Companies

Information Note No 229/CD of 9 November 2011 – The Infarmed clarified that Marketing Authorization holders may disclose on their websites, information regarding their medicinal products, as long as, it consists in a faithful reproduction of the medicinal product packages and the literal and entire reproduction of the informative leaflet or the summary of the medicinal product characteristics, as authorized, and if this information is subjected to a selection, treatment or manipulation, it may be considered that an advertising aim is at stake, in which case the content of the advertising will be analyzed according to the legal framework of advertising of medicinal products.

Addition to Information Note No 229/CD of 9 November 2011 – The Infarmed adds that, after the decision of the Supreme Court of 5 May 2011, it is admissible that, the information related to medicinal products subjected to medical prescription, reimbursed or not, and subject to certain conditions, may be disclosed.

- Expiry of Reimbursements (November 2011)

Resolution of the Board of INFARMED of 21 November, 2011 – Publishes the final List of medicinal products regarding which it was decided the expiry of

the reimbursement, as a result of the lack of trade, during November 2011.

- Hydrocortone – Supply Rupture

Information Note No 244/CD of 25 November 2011 – Informs that Hydrocortone medicinal product, is not being commercialized, even though the owner of the marketing authorization of the medicinal product, *Auden McKenzie* (Pharma Division) Ltd., has not formally notified the Infarmed, for the reason Infarmed presents alternative solutions.

- Commercialization of Reimbursed Medicinal Products

Information Note No 244/CD of 25 November 2011 – Aims to clarify Infarmed's actions in the specific case of reimbursed medicinal products, and in the situations where the holder of the marketing authorization/local representative has not initiated the effective commercialization. In this case, the Infarmed will initiate the systematic revision of the commercialization of the reimbursed medicines, on the basis of data declared by the holder of the marketing authorization/local representative in respect to the commercialization rates.

- Suspension of the company Crossbridge Produtos Farmacêuticos Lda

Deliberation No 104/CD/2011 of 24 November 2011 – Revokes the deliberation No 179/CD/2011, of 27-10-2011, of the suspension of the activity of Crossbridge Produtos Farmacêuticos Lda activity.

- New Prices for Medicinal Products

Joint Informative Note No 001of 7 December 2011 – Following the publication of the Decree-Law No 112/2011, which approved the new pricing legal framework of reimbursed medicinal products for human use, subject to medical prescription and not subjected to medical prescription, the Infarmed clarifies and recommends for the correct implementation of the Decree-Law and to avoid situations of rupture of supply to the populations.

- Falsified Medicinal Product Directive 2011/62/UE

Information Note No 262/CD of 20 December 2011 – Launches the public consultation, until 27 April of 2012, regarding the options for the implementation of the requirements set forth regarding the unique identifier of the safety features applied to the medicinal products, which became mandatory with the Directive 2011/62/UE that introduces a new legal framework which aims to protect the functioning of the internal market of the medicinal products and guarantees a high level of protection of public health against counterfeit medicinal products.

Information Note No 263/CD of 20 December 2011 – Launches the public consultation, until the 23 March 2012, regarding the options for the implementation of the requirements regarding the import of active substances to the European Union, also in respect to Directive 2011/62/UE.

- Commercialization Status of Medicinal Products on Infomed

Information Note No 254/CD of 12 December 2011 – Informs that to improve the information that is provided, the Infomed database now includes a field related to the status of commercialization of each package of medicinal products.

- Update of the Reference Pricing System in the Reimbursement of Medicinal Products by the NHS

Information Note No 253/CD of 9 December 2011 – Publishes the List of homogeneous Groups in force in the first quarter of 2012. The reference prices and the homogeneous Groups approved for the Quarter initiated in October 2011 were updated, 19 new homogeneous Groups were created and two new INN were included in the system - Esomeprazol e Levetiracetam – resulting from the commercialization of new generics for which new reference prices were approved.

- Quick Tests for the Detection of HIV1/ 2

Infarmed publishes a List of medical devices for *in vitro* diagnosis (Annex II, A List, for the detection, confirmation and quantification, in human samples, of markers of infection by HIV (HIV 1 and 2 – Quick Tests), to be updated every quarter.

- Publication of Marketing Authorization Requests of Generic Medicinal Products

Information Note No 265/CD of 21 December 2011 – Following Law No 62/2011 of 12th December, which created a new framework for disputes arising from intellectual property rights when reference medicinal products and generic medicinal products are at stake, the Infarmed will now publish from 22nd December onwards, on its webpage, certain data related to marketing authorizations requests regarding generics.

- Implementation of the New Orthographic Agreement in the Medicinal Products Information

Information Note No 275/CD of 28 December 2011 – To comply with Resolution No 8/2011 of the Presidency of the Council of Ministers, the Infarmed warns the holders of Marketing Authorizations, that they should implement the Orthographic Agreement of the Portuguese Language in the information regarding medicinal products, (summary of medicinal products characteristics, informative leaflet, labelling) whichever authorization procedure, from 1 January onwards.

IV. ACSS – NHS Centralised Purchases Authority

- Patients Moderating Fees

Regulation No 29 of 9 November, 2011 – Collection of Patients Moderating Fees based on the principle of Unique Treasury of the State.

Regulation No 36, 28 December, 2011 – Means to be used to verify situations of exemption of the payment of Patients Moderating Fees.

Regulation No 37, 28 December, 2011 – Exemption of the collection of Patients Moderating Fees and calculation of the values to be charged.

Regulation No 38, 28 December, 2011 – Trial period for the implementation of the new legal framework of Patients Moderating Fees – until 15 April 2012.

- Complementary Means of Diagnosis and Treatment

Informative Note No 35 of 16 December 2011 – Electronic Prescription of Complementary Means of Diagnosis and Therapeutic (MCDT).

VI. COMUNICATIONS – European Documents

- Utilization of Biocidal Products

Position (EU) No 11/2011 of the Council, adopted on the 21st of July, published in the Official Journal of the European Union, 1 November 2011 – Envisages the adoption of a Regulation of the European Parliament and of the Council concerning the making available on the market and use of biocidal products**.**

- Concentration Carlyle/H&F/Pharmaceutical Product Development

Communication 2011/C 323/09, of the European Commission, published in the Official Journal of the European Union of 5 November 2011 - Prior Notification of a Concentration (Case COMP/M.6423 — Carlyle/H&F/Pharmaceutical Product Development) — Candidate case for simplified procedure.

- Concentration J&J/Synthes

Communication 2011/C 335/01, of the European Commission, published in the Official Journal of the European Union of 16 November 2011 - Initiation of proceedings (Case COMP/M.6266 — J&J/Synthes).

- Concentration Südzucker/ED & F Man

Communication 2011/C 335/03, of the European Commission, published in the Official Journal of the European Union of 16 November 2011 - Initiation of proceedings (Case COMP/M.6286 — Südzucker/ED & F Man).

- Concentration Dow/Mitsui/Brazilian Polyethylene

Communication 2011/C 336/03, of the European Commission, published in the Official Journal of the European Union of 17 November 2011 - Non-opposition to a notified concentration (Case COMP/M.6391 — Dow/Mitsui/Brazilian Polyethylene JV).

- Concentration Waterland/Alychlo/Omega Pharma

Communication 2011/C 339/13, of the European Commission, published in the Official Journal of the European Union of 19 November 2011 - Prior notification of a concentration (Case COMP/M.6401 — Waterland/Alychlo/Omega Pharma).

- Concentration Apax/Kinetic Concepts

Communication 2011/C 341/03, of the European Commission, published in the Official Journal of the European Union of 22 November 2011 - Non-opposition to a notified concentration (Case COMP/M.6343 — Apax/Kinetic Concepts).

- Concentration Buitenfood/Ad van Geloven Holding/JV

Communication 2011/C 341/07, of the European Commission, published in the Official Journal of the European Union of 22 November 2011 - Prior notification of a concentration (Case COMP/M.6321 — Buitenfood/Ad van Geloven Holding/JV).

- Concentration Arla Foods/Allgauland

Communication 2011/C 343/03, of the European Commission, published in the Official Journal of the European Union of 23 November 2011 - Non-opposition to a notified concentration (Case COMP/M.6348 — Arla Foods/Allgauland).

- Concentration DSM/Roquette/JV

Communication 2011/C 343/08, of the European Commission, published in the Official Journal of the European Union of 23 November 2011 - Prior notification of a concentration (Case COMP/M.6432 — DSM/Roquette/JV) — Candidate case for simplified procedure.

- Concentration Oaktree/Panrico

Communication 2011/C 344/09, of the European Commission, published in the Official Journal of the European Union of 24 November 2011 - Prior notification of a concentration (Case COMP/M.6430 — Oaktree/Panrico).

- Concentration Cargill/KoroFrance

Communication 2011/C 353/03, of the European Commission, published in the Official Journal of the

European Union of 3 December 2011 - Non-opposition to a notified concentration (Case COMP/M.6383 — Cargill/KoroFrance).

- Concentration Gilde/Eismann

Communication 2011/C 353/04, of the European Commission, published in the Official Journal of the European Union of 3 December 2011 - Non-opposition to a notified concentration (Case COMP/M.6394 — Gilde/Eismann).

- Concentration Carlyle/H&F/Pharmaceutical Product Development

Communication 2011/C 353/06, of the European Commission, published in the Official Journal of the European Union of 3 December 2011 - Non-opposition to a notified concentration (Case COMP/M.6423 — Carlyle/H&F/Pharmaceutical Product Development).

- Good Labeling Practice

Communication 2011/C 358/07, of the European Commission, published in the Official Journal of the European Union of 8 December 2011 – Communication related to the Code of good labeling practice for pet food.

- Community Action in the Field of Health

Communication 2011/C 358/08, of the European Commission, published in the Official Journal of the European Union of 8 December 2011 – Call for applications 2012 — Second programme of Community action in the field of health (2008-2013).

- Children Healthcare

Communication 2011/C 361/04, of the European Commission, published in the Official Journal of the European Union of 10 December 2011 – About early detection and treatment of communication disorders in children, including the use of e-Health tools and innovative solutions.

Communication 2011/C 361/05, of the European Commission, published in the Official Journal of the European Union of 10 December 2011 – About prevention, early diagnosis and treatment of chronic respiratory diseases in children.

- Concentration Evonik Degussa/Treibacher Industries/JV

Communication 2011/C 371/02, of the European Commission, published in the Official Journal of the European Union of 20 December 2011 – Non-opposition to a notified concentration (Case COMP/M.6431 — Evonik Degussa/Treibacher Industries/JV).

- Conference on Biological Diversity

Communication 2011/C 371 E/04, of the European Parliament, published in the Official Journal of the European Union of 20 December 2011 – Refers to the strategic objectives for the 10th Meeting of the Conference of the Parties to the Convention on Biological Diversity (CBD), to be held in Nagoya (Japan) from 18 to 29 October 2010.

- Health Care Systems in sub-Saharan Africa and Global Health

Communication 2011/C 371 E/06, of the European Parliament, published in the Official Journal of the European Union of 20 December 2011 – Refers to health care systems in sub-Saharan Africa and global health (2010/2070(INI)).

- Marketing Authorizations within the European Union

Communication 2011/C 383/01, of the European Commission, published in the Official Journal of the European Union of 30 December 2011 - Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 September 2011 to 31 October 2011 *(Published pursuant to Article 13 or Article 38 of Regulation (EC) No 726/2004 of the European Parliament and of the Council)*

Communication 2011/C 383/02, of the European Commission, published in the Official Journal of the European Union of 30 December 2011 - Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 September 2011 to 31 October 2011 *(Decisions taken pursuant to Article 34 of Directive 2001/83/EC or Article 38 of Directive 2001/82/EC).*

IV. EUROPEAN CASE-LAW

- Cosmetics

Case C-439/09: Judgment of the Court (Third Chamber) of 13 October 2011 (reference for a preliminary ruling from the Cour d'appel de Paris (France)).

I. Reference for a preliminary ruling — Cour d'appel de Paris — Competition — General and absolute ban on internet sales of cosmetics and personal care products imposed by the supplier on authorised distributors in the context of a selective distribution network — Obligation to sell such products in a physical space in which a qualified pharmacist must be present — 'Hardcore' restriction of competition by object under Article 81(1) EC which cannot benefit from a block exemption under Commission Regulation No 2790/1999 of 22 December 1999 on the application of Article 81(3) of

the Treaty to categories of vertical agreements and concerted practices (OJ 1999 L 336, p. 21) — Possibility of benefiting from an individual exemption under Article 81(3) EC

II. *Article 4(c) of Commission Regulation (EC) No 2790/1999 of 22 December 1999 on the application of Article 81(3) of the Treaty to categories of vertical agreements and concerted practices must be interpreted as meaning that the block exemption provided for in Article 2 of that regulation does not apply to a selective distribution contract which contains a clause prohibiting de facto the internet as a method of marketing the contractual products. However, such a contract may benefit, on an individual basis, from the exception provided for in Article 101(3) TFEU where the conditions of that provision are met.*

- Human Embryonic Stem Cells

Case C-34/10: Judgment of the Court (Grand Chamber) of 18 October 2011 (reference for a preliminary ruling from the Bundesgerichtshof — Germany).

I. Reference for a preliminary ruling — Bundesgerichtshof — Interpretation of Article 6(1) and (2)(c) of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (OJ 1998 L 213, p. 13) — Extraction, for the purposes of scientific research, of precursor cells from human embryonic stem cells taken from a blastocyst, which is no longer capable of developing into a human being — Exclusion from patentability of that process as 'use of human embryos for industrial or commercial purposes'? — Concept of 'human embryos' and 'uses for industrial or commercial purposes'

II. Article 6(2)(c) of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions must be interpreted as meaning that:

— *any human ovum after fertilisation, any non-fertilised human ovum into which the cell nucleus from a mature human cell has been transplanted, and any non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis constitute a 'human embryo';*

— *it is for the referring court to ascertain, in the light of scientific developments, whether a stem cell obtained from a human embryo at the blastocyst stage constitutes a 'human embryo' within the meaning of Article 6(2)(c) of Directive 98/44.*

III. The exclusion from patentability concerning the use of human embryos for industrial or commercial purposes set out in Article 6(2)(c) of Directive 98/44 also covers the use of human embryos for purposes of scientific research, only use for therapeutic or diagnostic purposes which is applied to the human embryo and is useful to it being patentable.

IV. *Article 6(2)(c) of Directive 98/44 excludes an invention from patentability where the technical teaching which is the subject-matter of the patent application requires the prior destruction of human embryos or their use as base material, whatever the stage at which that takes place and even if the description of the technical teaching claimed does not refer to the use of human embryos.*

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