NEWS LEXTTER

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LIFE SCIENCES

EDITORIAL

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EDITORIAL CONTENTS

LIFE SCIENCES NEWS

What does a carbon nanotube have in common with a genetic test, a stem cell, a sperm or egg donation, a transgenic and a DNA chip? They all belong to the vast world of new technologies brought about by science and have launched new expectations for the diagnosis, prevention and treatment of disease as well as new areas of practice and new possibilities in practically every sector of activity. They are part of the Life Sciences which encompass the areas of biotechnology, biomedicine and environment in everything involving research, technology transfer and use. This is why a Life Sciences team needs to have a dynamic and multi-disciplinary profile and aware of its responsibility as regards progress and the future.

Our multi-disciplinary Life Science team, which today launches the first of many newsletters, seeks to mirror this dynamic force by developing the necessary skills to provide legal advice in the new areas of scientific knowledge and the new biomedical technologies which, in terms of innovation and development, pose the greatest challenges of the last few decades.

This is why a Life Sciences team needs to have a dynamic and multi-disciplinary make-up and be aware of its responsibility as regards progress and the future.

TEAM OF LIFE SCIENCES
(FROM THE LEFT TO THE RIGHT)
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ELIANA BERNARDO
MARTA COSTA
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(NOT IN THE PICTURE BUT ALSO A MEMBER OF THE TEAM)
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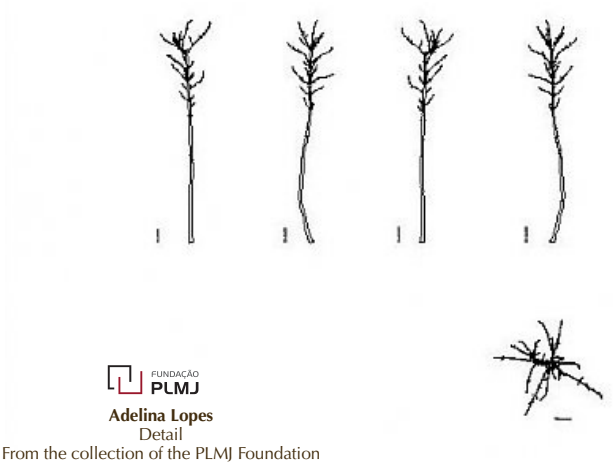
Stem Cell Banks



FUNDAÇÃO PLMJ
Adelina Lopes
Detail
From the collection of the PLMJ Foundation

Regulation and positioning within the legal regime of quality and safety standards for the donation, collection, testing, preservation, storage and distribution of human tissues and cells - the entry into force of Law 12/2009 of 26 March.

The entry into force of Law 12/2009 on 27 March marked the beginning of an important chapter in the long-awaited regulation of stem cell banks, not only of umbilical cord blood but also of bone marrow, reproductive and embryonic stem cells. This legislation shows how complex this matter is – from the donation to the use of tissues and cells of human origin in human beings. It involves umbilical cord cell banks. Sperm and egg banks. Embryo banks. Among others.

The legislation names the bodies that are responsible for enforcing compliance with the technical requirements: the **ASST** (Blood and Transplant Services Authority) and the **CNPMA** (National Council for Medically-Assisted Procreation), the latter of which is restricted to matters related to reproductive cells and human embryo stem cells. It also specifies their authorisation powers in respect of the activities concerned, as well as inspection and control measures.

A **national tissue and cell network** has been set up which comprises collection units, tissue and cell banks and the bodies responsible for their use (which does not cover reproductive cells, embryonic stem cells and other cells and tissues collected for use in medically-assisted procreation techniques).

The legislation also lays down rules for the import and export of human tissues and cells and the exact requirements for the **collection** of tissues and cells, particularly with regard to donor selection, consent to the donation, laboratory testing, data safety and privacy guarantees, as well as requirements for the quality and safety of tissues and cells (ranging from the people in charge and the staff at the collection units, to the banks and bodies responsible for their use, through to the receipt of tissues and cells and their processing and storage conditions, all the way to labelling, distribution, etc.).

There are three fundamental points in this regard:

1. In the case of **umbilical cord blood banks** – this is the very first time the law has laid down rules governing their functioning and it establishes the possibility for public but also private banks to exist. In the former, like in many European countries, the cells are accessible to all patients who are therapeutically indicated for their use (including the actual donor);

2. Clear specific rules have been established not only with regard to **consent** for the donation and the use of tissues and cells, but also regarding the information to be provided to the donors;

3. In terms of consent, the legislation lays down the limits for possible u**ses of the tissues and cells** apart from their initially intended ends and includes specific instructions for their elimination, which has so far been one of the biggest loopholes with regard to other uses of the tissues.

In view of the complexity of the legislation now in force and its practical ramifications, even in the implementation of the permitted activities and the operating of the tissue and cell banks and units, as well as all the remaining issues linked to this sensitive activity, there is no doubt that we shall be returning to the most important themes in the future.

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Market Authorisation – Revolution in sight?

It has been the settled jurisprudential view in this country that, as far as granting AIMs[1] is concerned, INFARMED is only responsible for ensuring that each medicinal product meets quality, safety and effectiveness requirements, not for guaranteeing whether or not any medicinal product is or may be in breach of third party patents.

This view has come about as a result of two different factors: on the one hand, from the fact that the legislation governing the placement of medicinal products on the market[2] makes no provision for the industrial property rights of similar medicinal products to have expired as a requirement for granting an AIM (not even in the case of generics) and on the other, the fact that granting an AIM is a merely instrumental act to the act of marketing any medicinal product which may be in potential breach of patent rights.

Around a month ago, however, this view was turned upside down by the Sintra Administrative and Tax Court when it handed down two decisions which are diametrically opposed to the current status quo. The Court saw fit to cancel the AIMs that had been granted to six generic medicinal products owing to the fact – which was common ground – that these medicinal products were in breach of the patent for the similar reference medicinal product.

Regardless of any basic position we may hold with regard to the substantive question, these decisions have raised important practical and philosophical issues, particularly at a time when there is an increasing number of disputes right across Europe between the main pharmaceutical brands and the generic companies.

In practical terms, what the Sintra Court said was that INFARMED, in addition to its obligation to ensure that medicinal products which receive AIMs are safe, effective and of the necessary quality, should also have to guarantee that they are not in infringement of any third party industrial property rights. Were these decisions to be upheld, the AIM would operate as a type of negative clearance, showing that the medicinal product which received the AIM was not in breach of any existing patent.

At present, neither Infarmed nor any other Portuguese body has the capacity to provide such an absolute guarantee. Unlike the case, for example, with brand names or company names, there is not (nor is there likely to be) a database recording every existing patent where it is possible to insert all the data about a new product or manufacturing process and automatically check the existence or otherwise of disputes.

Nevertheless, it will be of some interest to see to what extent a regulatory authority which is primarily charged with looking out for the quality and safety of medicinal products – which goes hand-in-hand with the protection of public health – should have to channel its energies towards investigating rights such as industrial property rights, which are private in nature.

It will be interesting to follow the course of the developments in respect of these two decisions and see to what extent the higher courts will uphold the view of the Sintra Administrative Court. If this should be the case, we may find ourselves in the throes of a revolution with regard to the placement of medicinal products on the market or, from a less optimistic point of view, at a dead-end.

[1] Marketing authorisation.
[2] Decree-law 176/2006, of 30 August, better known as the "Medicine Law".

The legalisation of the biowill

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For the past years the need to create a legislative framework for the so-called "biowill (or "vital will") has been subject of an intense debate in several neighbouring countries. In the meanwhile, along those years, several countries have adopted legislative solutions for such a problematic topic. That is, they have allowed an individual to give instructions as to (at least) the treatments to which he or she wishes to be subjected in the event of any future incapacity.

Spain was one of the first countries to legislate on this matter (Law 41, of 14 November 2002), with the view of dignifying the autonomy of such patients. Indeed, by means of preventative instructions, such patients can, make known their "future will/intentions" with regard to the cures and therapies to which they should be submitted, as well as the destination of their organs and body, after their death. Similarly, in France, the Code de la Santé Publique was amended (Law 2005-370) to include the vital will.

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The closest situation to the one in Portugal, where no specific law exists at present, is Italy. However, in Italy, the vital will has already taken greater steps in the crusade of being consecrated in the legislation. At present, a bill is being debated in the parliament, driven by the recent tragic case of Eluana, the girl who spent over ten years in a coma and was denied artificial feeding, thus causing her death by dehydration.

In Portugal, the society seems to be more open to and interested in this topic, which is now frequently mentioned in the media. There appears to be receptiveness towards the discussion of such matters and it is therefore time to bring it to the forefront, for the sake of constitutional rights such as the right to self-determination and human dignity.

At present, a bill is being debated in the parliament, driven by the recent tragic case of Eluana, the girl who spent over ten years in a coma and was denied artificial feeding, thus causing her death by dehydration.

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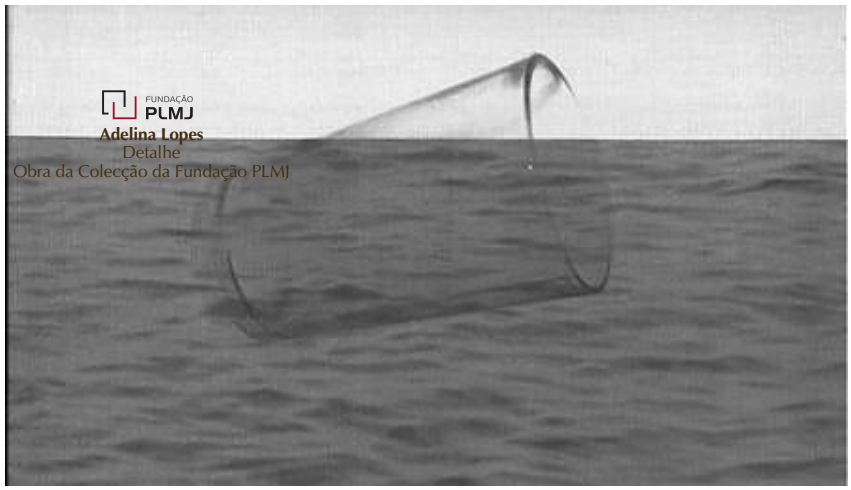
Dispensing Medicinal Products to People's Homes and Via Internet



The legal regime for pharmacies set out in Decree-Law 307/2007, of 31st of August, made it possible for non-hospital pharmacies and other over-the-counter shops to dispense medicinal products to peoples' home and to accept such orders via internet. Therefore, medicinal products no longer need to be dispensed in person and the customer may order the medicinal product over the phone, by fax or e-mail or even through the internet.

The conditions and requirements for dispensing medicinal products to people's homes and via internet were ruled by Ministerial Order 1427/2007, of 2nd of November, which provides: a) that a medicinal product may only be delivered to the home by the pharmacy or over-the-counter shop from which it was ordered; and, b), it must be delivered under the supervision of a chemist in the case of pharmacy delivery, or an over-the-counter shop assistant in the case of an over-the-counter shop.

As in cases where medicinal products are dispensed by pharmacy staff at the pharmacy, all the information necessary for its appropriate use must be given to the patient when medicinal products are delivered to the home, and, of course, only pharmacies may dispense prescription medicinal product upon presentation of the prescription.

Moreover, the delivery of medicinal products to peoples's homes entails greater care in relation to dispensing by person, especially in terms of the conditions of transport between the pharmacy or the over-the-counter shop and the patient's home. In particular, medicinal products must be transported in such a way as to ensure that: (i) their identification is not erased, (ii) they neither contaminate, nor are contaminated by other materials, (iii) there is no spillage, breakage or theft, (iv) they are carried in safety and (v) they are not exposed to inappropriate heat, cold, light, humidity or other adverse factors.

Furthermore, the dispensing of medicinal products to people's homes is restricted to the municipality where the pharmacy is located and to the adjacent municipalities. While the legislation only includes pharmacies in this restriction, we believe that it should be taken to extend to over-the-counter shops.

All pharmacies and over-the-counter shops that dispense medicinal products to people's homes, regardless of how the product is ordered, are required to register the orders including a reference to the name of the medicinal product, the amount dispensed and the municipality of delivery, and must provide this information to INFARMED whenever requested.

Pharmacies and over-the-counter shops that intend to dispense medicinal products via internet must comply with

Pharmacies and over-the-counter shops that intend to dispense medicinal products via internet must comply with certain special rules, including having their own individual website, while pharmacies or over-the-counter shops that are held, managed or operated by the same person or company may share a website.

certain special rules, including having their own individual website, while pharmacies or over-the-counter shops that are held, managed or operated by the same person or company may share a website.

The said website must provide at least the following information: (i) the price of the services regarding the dispensing of medicinal products and their delivery to the home (e.g. if a delivery fee is charged), (ii) accepted methods of payment, (iii) geographical range of the service, (iv) estimated time for the delivery of the medicinal products ordered, and (v) the name of the chemist in charge of the pharmacy.

The dispensing of medicinal products to people's homes through the website requires the latter's address is provided in advance to INFARMED – Autoridade Nacional do Medicamento e Produtos de Saúde, I.P. which publishes a list of the internet sites of which it has been properly informed on its own internet site.

Brief Note

Constitutional Court Ruling 101/2009 on the application for a declaration of the illegality and unconstitutionality of Law 32/2006, of 26 July (the Medically-Assisted Procreation Law) was published in the Official Gazette *(Diário da República, II Série)* on 1 April 2009. The Constitutional Court decided not to grant the requested unconstitutionality ruling.

In its next newsletters, the Life Sciences multi-disciplinary team will continue to discuss the legally problematic question of Medically-Assisted Procreation and the most relevant issues raised by this topic.

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"Portuguese Law Firm of the Year"
Chambers Europe Excellence 2009, IFLR Awards 2006, Who's Who legal Awards 2006, 2008, 2009

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ACQ Finance Magazine, 2009

"Best Portuguese Law Firm for Client Service"
Clients Choice Award - International Law Office, 2008

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International Tax Review - Tax Awards 2006, 2008

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